



January 10, 2003

9281 '03 JAN 15 09:45

Dockets Management Branch
HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION
(ANADA SUITABILITY PETITION)

First Priority, Inc hereby submits this petition under Section 512 (n) (3) of the Federal Food, Drug and Cosmetic Act to seek permission from the Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, to file a supplement to an Approved Abbreviated New Animal Drug Application (ANADA) which differs in the route of administration from the innovator product.

A. Action requested

First Priority, Inc seeks permission to file a supplemental ANADA for a generic equivalent of the innovator product, Privermectin™ Equine Oral Liquid, ANADA 200-321, First Priority, Inc., which differs from the innovator product in the route of administration.

The proposed Privermectin™ Equine Oral Liquid route of administration is to be labeled:

Privermectin™ Equine Oral Liquid for Horses is formulated for administration as an oral drench.

The innovator product, Privermectin™ Equine Oral Liquid is labeled with the following route of administration:

Privermectin™ Equine Oral Liquid for Horses is formulated for administration by stomach tube (nasogastric intubation) or as an oral drench.

First Priority, Inc is requesting this change in the route of administration, deleting all reference to route of administration by stomach tube (nasogastric intubation), enabling the labeling of Privermectin™ Equine Oral Liquid for sale as an over-the-counter (OTC) product. The innovator Privermectin™ Equine Oral Liquid is an approved new animal drug (ANADA 200-321) which is labeled: CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

Three copies of the approved innovator 100 mL labeling and three copies of all proposed labeling for the requested change in route of administration are attached. Appropriate changes for the change in route of administration and the change to OTC status have been included in the proposed labeling, in particular, advice to consult with a veterinarian consistent with the labeling for the OTC product, Eqvalan® Paste for Horses, NADA 134-314.

03P-0013

CPI

B. Statement of grounds

Under provisions of the Federal Food, Drug, and Cosmetic Act, Section 512 (n)

(3) *If a person wants to submit an abbreviated application for a new animal drug--*

(A) whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug, or

(B) whose use with other animal drugs in animal feed differs from that of an approved new animal drug,

such person shall submit a petition to the Secretary seeking permission to file such an application.

This ANADA Suitability Petition qualifies under the provisions of the Federal Food, Drug, and Cosmetic Act, Section 512 (n) (3) (A) in that permission is sought to change only the route of administration of an approved new animal drug.

The active ingredient in Privermectin™ Equine Oral Liquid, ivermectin, will be the same as the innovator Privermectin™ Equine Oral Liquid and will be included in the generic product at the same concentration and dosed at the same rate and frequency as the innovator:

- A. DOSAGE FORM: Ivermectin Oral Liquid 10 mg/mL
- B. ROUTE OF ADMINISTRATION: Privermectin™ Equine Oral Liquid is to be administered by oral drench.
- C. RECOMMENDED DOSAGE: The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) body weight.

C. Environmental impact

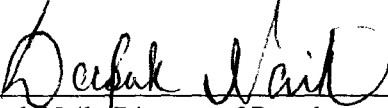
First Priority, Inc requests that this petition be considered for categorical exclusion under 21 CFR 25.24.

D. Economic impact

An economic impact analysis will be provided if requested after review of this petition.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Deepak Naik, Director of Regulatory Affairs
First Priority, Inc
1585 Todd Farm Drive
Elgin, IL 60123-1146

DIRECTIONS: For the treatment and control of large strongids, small strongids, habronema, pinworm, roundworm (ascarids), threadworms, large-mouth stomach worms, bots, lungworms, summer sores and summer skin irritation.

DOSE: 200 mg of ivermectin per kilogram (21 mg/lb) of body weight. Each mL contains sufficient ivermectin to treat 170 lb (80 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.

See package insert for complete instructions and use directions.
Recorder No. OM00PCARE
Iss. 08-01
Lot No. Exp. Date

NDC# 8880-204-10
Priority Care

Ivermectin[®]
Equine Oral Liquid

(ivermectin)
Liquid for Horses - 10 mg per mL
For Veterinary Use Only

Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.
Net Contents: 100 mL
ANADA 200-321, Approved by FDA

WARNING: Do not use in horses intended for human consumption.

Directions: Administer 10 mL of Ivermectin Equine Oral Liquid per 170 lb (80 kg) of body weight. Administer once daily for 3 consecutive days. Administer with food.

Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

Net Contents: 100 mL

0-01-462803-20
0829710-1

DIRECTIONS: For the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (roundworms), threadworms, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous anthrax.

RECOMMENDED DOSE: 200 mcg of ivermectin per kilogram (91 mg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 to 220 kg of body weight; 10 mL will treat an 1100 to 2200 kg horse.

See package insert for complete instructions and use directions.

Reorder No. OMS0PCAF6

Iss. 09-01

Lot No. Exp. Date

NDC 58820-204-10
Priority Care 

Ivermectin™
Equine Oral Liquid

(ivermectin)
Liquid for Horses - 10 mg per mL
For Veterinary Use Only

Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

Net Contents: 100 mL
ANADA 200-321, Approved by FDA

WARNING: Do not use in horses intended for human consumption.

Caution: Ivermectin (ivermectin) Oral Liquid is a potent anthelmintic and should be used only in horses. It is not intended for use in other species. Ivermectin Oral Liquid is not to be used in horses intended for human consumption. It is not to be used in horses intended for human consumption. It is not to be used in horses intended for human consumption.

Keep this liquid out of the reach of children.

Store this liquid at controlled room temperature (20°-25°C or 68°-77°F). Protect from light. Do not use if the liquid is discolored or contains particles.

Keep this liquid out of the reach of children.

ONE


FIRST PRIORITY, INC.

INDICATIONS: For the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous protozoostomiasis.

RECOMMENDED DOSE: 250 mcg of ivermectin per kilogram (51 mg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.

See package insert for complete instructions and use directions.

Product No. OMS80PCARE

Iss. 09-01

Lot No. Exp. Date

NDC# 58020-204-10

**Priority
Care**

**Privermectin™
Equine Oral Liquid**

(ivermectin)

**Liquid for Horses - 10 mg per mL
For Veterinary Use Only**

Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

Net Contents: 100 mL

ANADA 200-321, Approved by FDA

Warnings:
Keep out of reach of children.
Do not use if the seal is broken or the container is damaged.

Directions:
Give orally to horses. Administer 10 mg (1 mL) per 100 kg (220 lb) of body weight. Repeat treatment 14 days later with 10 mg (1 mL) per 100 kg (220 lb) of body weight.

Precautions:
Do not use in pregnant mares or broodmares.

Storage:
Store in original container between 40°-60°F (4°-15°C). Do not freeze. Protect from light. Do not use if the seal is broken or the container is damaged.

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NDA# 141-294-10

Priority Care

Privermectin™ Equine Oral Liquid
(ivermectin)
Liquid for Horses - 10 mg per mL
For Veterinary Use Only

For Animal Use Only - Keep Out of Reach of Children
Net Content: 100 mL
AMANDA PRODUCT, Approved by FDA

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of pinworm, *Pinworm*™ Equine Oral Liquid is indicated for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, hairworms, summer sores and cutaneous onchocerciasis.

RECOMMENDED DOSE: 500 mcg of ivermectin per kilogram of body weight of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.

See package insert for complete indications and use directions.

Register No. 02699PC Exp. Date 12-08
12/10

NO VARNISH

PRECAUTIONS:

WARNING: Do not use in horses intended for food purposes.

CAUTION: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other species as severe adverse reactions, including fatalities in dogs, may result. Puffing from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

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

STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Privermectin™ Equine Oral Liquid from light.

<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 water-borne organisms on which they feed. Do not contaminate lakes, streams, or ground water by direct application or by improper disposal of drug containers. Dispose of drug container in an approved landfill or by incineration.</p> <p>Note to Users: Swelling and itching reactions after treatment with Privermectin™ Equine Oral Liquid have occurred in horses carrying heavy infections of neck threadworm microfilariae, <i>Onchocerca</i> sp. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur.</p> <p>Healing of summer sores involving extensive tissue changes may require other therapy in conjunction with Privermectin™ Equine Oral</p> <p style="text-align: center;">8</p>	<p>Liquid. Reinfestation, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.</p> <p>Package Information: Privermectin™ Equine Oral Liquid is available in 100 mL, 200 mL, 500 mL, and 960 mL (32.46 fl oz.) plastic bottles. Each bottle contains sufficient ivermectin to treat 500 kg (1100 lb) horses as follows:</p> <p>100 mL 10-500 kg (1100 lb) horses 200 mL 20-500 kg (1100 lb) horses 500 mL 50-500 kg (1100 lb) horses 960 mL 96-500 kg (1100 lb) horses</p> <p>Contents may be poured into a graduated cylinder for dose measurement. Alternatively, a clean syringe may be inserted directly into the bottle to draw off the appropriate dose.</p> <p style="text-align: center;">10</p>	<p style="text-align: center;">Priority Care <i>would you walk for less?</i> FIRST PRIORITY, INC., Eggen, IL 60123-1146, U.S.A.</p> <p style="text-align: center;">11</p>	<p>PRECAUTIONS:</p> <p>WARNING: Do not use in horses intended for food purposes.</p> <p>CAUTION: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other species as severe adverse reactions, including fatalities in dogs, may result. Puffing from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.</p> <p>Keep this and all drugs out of the reach of children.</p> <p>STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Privermectin™ Equine Oral Liquid from light.</p> <p style="text-align: center;">12</p>	<p style="text-align: center;">FOR VETERINARY USE ONLY</p> <p style="text-align: center;">Privermectin™ Equine Oral Liquid (ivermectin) Liquid for Horses - 10 mg per mL</p> <table border="0"> <tr> <td>Introduction</td> <td style="text-align: right;">Page</td> </tr> <tr> <td>Description</td> <td style="text-align: right;">2</td> </tr> <tr> <td>Indications</td> <td style="text-align: right;">3, 4</td> </tr> <tr> <td>Dosage</td> <td style="text-align: right;">4</td> </tr> <tr> <td>Administration</td> <td style="text-align: right;">4, 5, 6</td> </tr> <tr> <td>Suggested Parasite Control Program</td> <td style="text-align: right;">6</td> </tr> <tr> <td>Mode of Action</td> <td style="text-align: right;">6, 7</td> </tr> <tr> <td>Safety</td> <td style="text-align: right;">7, 8</td> </tr> <tr> <td>Precautions</td> <td style="text-align: right;">8</td> </tr> <tr> <td>Environmental Safety</td> <td style="text-align: right;">9</td> </tr> <tr> <td>Note to User</td> <td style="text-align: right;">9, 10</td> </tr> <tr> <td>Package Information</td> <td style="text-align: right;">10</td> </tr> </table> <p style="text-align: center;">1</p>	Introduction	Page	Description	2	Indications	3, 4	Dosage	4	Administration	4, 5, 6	Suggested Parasite Control Program	6	Mode of Action	6, 7	Safety	7, 8	Precautions	8	Environmental Safety	9	Note to User	9, 10	Package Information	10	<p>Introduction</p> <p>Privermectin™ Equine Oral Liquid (ivermectin) for Horses has been formulated for administration by oral drench. One low-volume dose is effective against important internal parasites, including the arterial stages of <i>Strongylus vulgaris</i>, and bots.</p> <p>Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents. Its convenience, broad-spectrum efficacy and safety margin make Privermectin™ Equine Oral Liquid an ideal parasite control product for horses.</p> <p>Privermectin™ is a registered trademark of First Priority, Inc., Eggen, IL 60123-1146.</p> <p>Product Description: Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents, which are isolated from fermentation of <i>Streptomyces avermitilis</i>. Privermectin™ Equine Oral Liquid is a clear, ready-to-use solution with each mL containing 1%</p> <p style="text-align: center;">2</p>
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Indications	3, 4																												
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Administration	4, 5, 6																												
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<p>ivermectin (10 mg), 0.2 mL propylene glycol, 80 mg polyorbate 80, 9 mg sodium phosphate monobasic monohydrate, 1.3 mg sodium phosphate dibasic anhydrous, 1 mg butylated hydroxytoluene, 0.1 mg disodium edetate, 3% benzyl alcohol and purified water q.s. ad 100%.</p> <p>Product Indications: Privermectin™ Equine Oral Liquid is indicated for the effective treatment and control of the following parasites or parasitic conditions in horses.</p> <p>Large Strongyles: <i>Strongylus vulgaris</i> (adults and arterial larval stages), <i>S. edentatus</i> (adults and tissue stages), <i>S. equinus</i> (adults).</p> <p>Tricodontophorus spp (adults)</p> <p>Small Strongyles - including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae), <i>Cyathostomum</i> spp.</p> <p><i>Cylicocyclus</i> spp, <i>Cylicostephanus</i> spp.</p> <p><i>Cylicodontophorus</i> spp.</p> <p>Pinworms (adults and fourth-stage larvae)</p> <p><i>Oxyuris equi</i></p> <p style="text-align: center;">3</p>	<p>Ascarids (adults and third- and fourth-stage larvae) <i>Parascaris equorum</i></p> <p>Hairworms (adults) <i>Trichostrongylus axei</i></p> <p>Large-mouth Stomach Worms (adults) <i>Habronema muscae</i></p> <p>Bots (oral and gastric stages) <i>Gastrophilus</i> spp</p> <p>Lungworms (adults and fourth-stage larvae) <i>Dictyocaulus armiti</i></p> <p>Intestinal Threadworms (adults): <i>Strongylides</i> <i>westerni</i></p> <p>Summer Sores caused by <i>Habronema</i> and <i>Draschia</i> spp; cutaneous third-stage larvae</p> <p>Dermatitis caused by neck threadworm microfilariae, <i>Onchocerca</i> sp.</p> <p>Dosage: Privermectin™ Equine Oral Liquid for Horses is formulated for administration by oral drench. The recommended dose is 200 mcg of ivermectin per kilogram (0.1 mcg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.</p> <p style="text-align: center;">4</p>	<p>Administration: Use a calibrated dosing syringe inserted into the bottle to measure the appropriate dose, or pour the Privermectin™ Equine Oral Liquid into a graduated cylinder for dose measurement. Use a clean syringe if accessing the bottle to avoid contaminating the remaining product.</p> <p>Administration by drench: For administration by oral drench, use of an undiluted dose is recommended. Clear the horse's mouth of any food material, elevate the horse's head, and using a syringe, deposit the appropriate dose in the back of the mouth. In order to avoid unnecessary coughing or the potential for material to enter the trachea and lungs, do not use excessive pressure (squirting), do not use a large (diluted) dose volume, and do not deposit the dose in the laryngeal area. Increased dose rejection may occur if the dose is deposited in the buccal space. Keep the horse's head elevated and observe the horse to insure the dose is retained.</p> <p style="text-align: center;">5</p>	<p>Suggested Parasite Control Program: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. Privermectin™ Equine Oral Liquid effectively controls gastrointestinal nematodes and bots in horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by <i>S. vulgaris</i>. With its broad spectrum, Privermectin™ Equine Oral Liquid is well suited to be the major product in a parasite control program.</p> <p>Mode of Action: Ivermectin, one of the avermectins, kills certain parasitic roundworms and ectoparasites such as mites and lice. The avermectins are different in their action from other 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.</p> <p style="text-align: center;">6</p>	<p>The 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.</p> <p>The enhancement of the GABA effect in arthropods such as mites and lice 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> <p>The principle 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>Safety: Privermectin™ Equine Oral Liquid may be used in horses of all ages including mares at any stage of pregnancy. Stallions may be treated</p> <p style="text-align: center;">7</p>	<p>without adversely affecting their fertility. These horses have been treated with no adverse effects other than those noted under Note to User.</p> <p>Precautions</p> <p>Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.</p> <p>• Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. Keep this and all drugs out of the reach of children.</p> <p>• Store in a tightly closed container at room temperature (between 15°-30°C, 59°-86°F).</p> <p>• Protect Privermectin™ Equine Oral Liquid from light.</p> <p>For customer service, contact First Priority, Inc. 1580 Todd Farm Drive Eggen, IL 60123-1146 1-800-600-4889</p> <p style="text-align: center;">8</p>																								

NDC 50222-204-10

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Privermectin™ Equine Oral Liquid is indicated for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and Onchocerca microfilariae.

RECOMMENDED DOSE: 500 mcg of ivermectin per kilogram (91 mcg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 to 150 kg (243 to 330 lb) body weight. 10 mL will treat an 1100 lb (500 kg) horse.

This package is not for complete indications and use directions.

Patented by CIBA-GEIGY, Inc. 12-02
Ciba, Ltd. Egg, Ltd.

NO VARNISH

Priority Care

Privermectin™
Equine Oral Liquid

(ivermectin)
Liquid for Horses - 10 mg per mL
For Veterinary Use Only

For Animal Use Only • Keep Out of Reach of Children
Net Contents: 100 mL

ANADA 200-201, Approved by FDA

PRECAUTIONS:

WARNING: Do not use in horses intended for food purposes.

CAUTION: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

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

STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Privermectin™ Equine Oral Liquid from light.

<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 water-borne organisms on which they feed. Do not contaminate lakes, streams, or ground water by direct application or by improper disposal of drug containers. Dispose of drug container in an approved landfill or by incineration.</p> <p>Note to User: Swelling and itching reactions after treatment with Privermectin™ Equine Oral Liquid have occurred in horses carrying heavy infections of neck threadworm microfilariae, <i>Onchocerca</i> sp. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur.</p> <p>Healing of summer sores involving extensive tissue changes may require other therapy in conjunction with Privermectin™ Equine Oral</p> <p style="text-align: center;">9</p>	<p>Liquid. Reinfestation, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.</p> <p>Package Information: Privermectin™ Equine Oral Liquid is available in 100 mL, 200 mL, 500 mL, and 900 mL (30.45 fl. oz.) plastic bottles. Each bottle contains sufficient ivermectin to treat 500 kg (1100 lb) horses as follows:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">100 mL</td> <td style="width: 85%;">10-500 kg (1100 lb) horses</td> </tr> <tr> <td>200 mL</td> <td>20-500 kg (1100 lb) horses</td> </tr> <tr> <td>500 mL</td> <td>50-500 kg (1100 lb) horses</td> </tr> <tr> <td>900 mL</td> <td>90-500 kg (1100 lb) horses</td> </tr> </table> <p>Contents may be poured into a graduated cylinder for dose measurement. Alternatively, a clean syringe may be inserted directly into the bottle to draw off the appropriate dose.</p> <p style="text-align: center;">10</p>	100 mL	10-500 kg (1100 lb) horses	200 mL	20-500 kg (1100 lb) horses	500 mL	50-500 kg (1100 lb) horses	900 mL	90-500 kg (1100 lb) horses	<p>Priority Care</p> <p><i>would you settle for less?</i></p> <p>FIRST PRIORITY, INC., Elgin, IL 60123-1146, U.S.A.</p> <p style="text-align: center;">11</p>	<p>PRECAUTIONS:</p> <p>WARNING: Do not use in horses intended for food purposes.</p> <p>CAUTION: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.</p> <p>Keep this and all drugs out of the reach of children.</p> <p>STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Privermectin™ Equine Oral Liquid from light.</p> <p style="text-align: center;">12</p>	<p>FOR VETERINARY USE ONLY</p> <p>Privermectin™ Equine Oral Liquid</p> <p>(ivermectin) Liquid for Horses - 10 mg per mL</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">Introduction</td> <td style="width: 20%; text-align: right;">Page</td> </tr> <tr> <td>Description</td> <td style="text-align: right;">2</td> </tr> <tr> <td>Indications</td> <td style="text-align: right;">3, 4</td> </tr> <tr> <td>Dosage</td> <td style="text-align: right;">4</td> </tr> <tr> <td>Administration</td> <td style="text-align: right;">4, 5, 6</td> </tr> <tr> <td>Suggested Parasite Control Program</td> <td style="text-align: right;">6</td> </tr> <tr> <td>Mode of Action</td> <td style="text-align: right;">6, 7</td> </tr> <tr> <td>Safety</td> <td style="text-align: right;">7, 8</td> </tr> <tr> <td>Precautions</td> <td style="text-align: right;">8</td> </tr> <tr> <td>Environmental Safety</td> <td style="text-align: right;">9</td> </tr> <tr> <td>Note to User</td> <td style="text-align: right;">9, 10</td> </tr> <tr> <td>Package Information</td> <td style="text-align: right;">10</td> </tr> </table> <p style="text-align: center;">1</p>	Introduction	Page	Description	2	Indications	3, 4	Dosage	4	Administration	4, 5, 6	Suggested Parasite Control Program	6	Mode of Action	6, 7	Safety	7, 8	Precautions	8	Environmental Safety	9	Note to User	9, 10	Package Information	10	<p>Introduction</p> <p>Privermectin™ Equine Oral Liquid (ivermectin) for Horses has been formulated for administration by oral drench. One low-volume dose is effective against important internal parasites, including the artrial stages of <i>Strongylus vulgaris</i>, and bots.</p> <p>Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents. Its convenience, broad-spectrum efficacy and safety margin make Privermectin™ Equine Oral Liquid an ideal parasite control product for horses.</p> <p>Privermectin™ is a registered trademark of First Priority, Inc., Elgin, IL 60123-1146.</p> <p>Product Description: Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents, which are isolated from fermentation of <i>Streptomyces avermectis</i>. Privermectin™ Equine Oral Liquid is a clear, ready-to-use solution with each mL containing 1%</p> <p style="text-align: center;">2</p>
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Dosage	4																																				
Administration	4, 5, 6																																				
Suggested Parasite Control Program	6																																				
Mode of Action	6, 7																																				
Safety	7, 8																																				
Precautions	8																																				
Environmental Safety	9																																				
Note to User	9, 10																																				
Package Information	10																																				

<p>ivermectin (10 mg), 0.2 mL propylene glycol, 80 mg polysorbate 80, 8 mg sodium phosphate monobasic monohydrate, 1.3 mg sodium phosphate dibasic anhydrous, 1 mg butylated hydroxytoluene, 0.1 mg disodium edetate, 3% benzyl alcohol and purified water q.s. ad 100%</p> <p>Product Indications: Privermectin™ Equine Oral Liquid is indicated for the effective treatment and control of the following parasites or parasitic conditions in horses:</p> <p>Large Strongyles: <i>Strongylus vulgaris</i> (adults and arterial stage stages), <i>S. edentatus</i> (adults and tissue stages), <i>S. equinus</i> (adults), <i>Triodontophorus</i> spp (adults)</p> <p>Small Strongyles - including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae) <i>Cyathostomum</i> spp., <i>Cylicocyclus</i> spp., <i>Cylicostephanus</i> spp., <i>Cylicodontophorus</i> spp.</p> <p>Pinworms (adults and fourth-stage larvae) <i>Oxyuris equi</i></p> <p style="text-align: center;">3</p>	<p>Ascarids (adults and third- and fourth-stage larvae) <i>Parascaris equorum</i></p> <p>Hairworms (adults) <i>Trichostrongylus axei</i></p> <p>Large-mouth Stomach Worms (adults) <i>Habronema muscae</i></p> <p>Bots (oral and gastric stages) <i>Gastrophilus</i> spp</p> <p>Lungworms (adults and fourth-stage larvae) <i>Dictyocaulus arnfieldi</i></p> <p>Intestinal Threadworms (adults) <i>Strongylus foecoris</i> wester</p> <p>Summer Sores caused by <i>Habronema</i> and <i>Draschia</i> spp. cutaneous third-stage larvae</p> <p>Dermatitis caused by neck threadworm microfilariae, <i>Onchocerca</i> sp.</p> <p>Dosage: Privermectin™ Equine Oral Liquid for Horses is formulated for administration by oral drench. The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) of bodyweight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.</p> <p style="text-align: center;">4</p>	<p>Administration: Use a calibrated dosing syringe inserted into the bottle to measure the appropriate dose, or pour the Privermectin™ Equine Oral Liquid into a graduated cylinder for dose measurement. Use a clean syringe if accessing the bottle to avoid contaminating the remaining product.</p> <p>Administration by drench: For administration by oral drench, use of an undiluted dose is recommended. Clear the horse's mouth of any food material, elevate the horse's head, and using a syringe, deposit the appropriate dose in the back of the mouth. In order to avoid unnecessary coughing or the potential for material to enter the trachea and lungs, do not use excessive pressure (squirting), do not use a large (diluted) dose volume, and do not deposit the dose in the laryngeal area. Increased dose rejection may occur if the dose is deposited in the buccal space. Keep the horse's head elevated and observe the horse to insure the dose is retained.</p> <p style="text-align: center;">5</p>	<p>Suggested Parasite Control Program: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. Privermectin™ Equine Oral Liquid effectively controls gastrointestinal nematodes and bots in horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by <i>S. vulgaris</i>. With its broad spectrum, Privermectin™ Equine Oral Liquid is well suited to be the major product in a parasite control program.</p> <p>Mode of Action: Ivermectin, one of the avermectins, kills certain parasitic roundworms and ectoparasites such as mites and lice. The avermectins are different in their action from other 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.</p> <p style="text-align: center;">6</p>	<p>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.</p> <p>The enhancement of the GABA effect in arthropods such as mites and lice 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> <p>The principle 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>Safety: Privermectin™ Equine Oral Liquid may be used in horses of all ages including mares at any stage of pregnancy. Stallions may be treated</p> <p style="text-align: center;">7</p>	<p>without adversely affecting their fertility. These horses have been treated with no adverse effects other than those noted under Note to User.</p> <p>Precautions</p> <ul style="list-style-type: none"> • Caution: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. • Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. Keep mite and all drugs out of the reach of children. • Store in a tightly closed container at room temperature (between 15° - 30°C, 59° - 86°F). • Protect Privermectin™ Equine Oral Liquid from light. <p>For customer service, contact First Priority, Inc. 1588 Todd Farm Drive Elgin, IL 60123-1146 1-800-850-4899</p> <p style="text-align: center;">8</p>
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WARNING: Consult your veterinarian for assistance in the diagnosis, treatment and control of intestinal, parasitic, pulmonary, pleuropneumonia, and other respiratory, bacterial, viral, and protozoal diseases, including strangles, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis.

INDICATIONS: Ivermectin 10 mg, 200 mg of ivermectin per kilogram (20 mg/100 lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight; 10 mL will treat an 1100 lb (500 kg) horse.

Use package insert for complete indications and use directions.

Product No. Q100000C Exp. Date Iss. 10-02

NO VARNISH

Priority Care
would you settle for less?
FIRST PRIORITY, INC.,
 Elgin, IL 60123-1146, U.S.A.

For Animal Use Only • Keep Out of Reach of Children
 Net Contents: 100 mL
 ANADA 260391, Approved by FDA

PRECAUTIONS: Do not use in horses intended for food purposes.

CAUTION: Privernectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

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

STORAGE: Store in a tightly closed container between 10°-30°C (50°-85°F). Protect Privernectin™ Equine Oral Liquid from light.

<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 water-borne organisms on which they feed. Do not contaminate lakes, streams, or ground water by direct application or by improper disposal of drug containers. Dispose of drug container in an approved landfill or by incineration.</p> <p>Note to User: Swelling and itching reactions after treatment with Privernectin™ Equine Oral Liquid have occurred in horses carrying heavy infections of neck threadworm microfilariae, <i>Onchocerca</i> sp. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur.</p> <p>Healing of summer sores involving extensive tissue changes may require other therapy in conjunction with Privernectin™ Equine Oral</p>	<p>Liquid. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.</p> <p>Package Information: Privernectin™ Equine Oral Liquid is available in 100 mL, 200 mL, 500 mL, and 960 mL (32.46 fl. oz.) plastic bottles. Each bottle contains sufficient ivermectin to treat 500 kg (1100 lb) horses as follows:</p> <p>100 mL 10-500 kg (1100 lb) horses 200 mL 20-500 kg (1100 lb) horses 500 mL 50-500 kg (1100 lb) horses 960 mL 96-500 kg (1100 lb) horses</p> <p>Contents may be poured into a graduated cylinder for dose measurement. Alternatively, a clean syringe may be inserted directly into the bottle to draw off the appropriate dose.</p>	<p>Priority Care <i>would you settle for less?</i> FIRST PRIORITY, INC., Elgin, IL 60123-1146, U.S.A.</p>	<p>PRECAUTIONS: Do not use in horses intended for food purposes.</p> <p>CAUTION: Privernectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.</p> <p>Keep this and all drugs out of the reach of children.</p> <p>STORAGE: Store in a tightly closed container between 10°-30°C (50°-85°F). Protect Privernectin™ Equine Oral Liquid from light.</p>	<p>FOR VETERINARY USE ONLY</p> <p>Privernectin™ Equine Oral Liquid (ivermectin) Liquid for Horses - 10 mg per mL.</p> <table border="1"> <tr><td>Description</td><td>Page</td></tr> <tr><td>Indications</td><td>2</td></tr> <tr><td>Dosage</td><td>2</td></tr> <tr><td>Administration</td><td>3, 4</td></tr> <tr><td>Suggested Parasite Control Program</td><td>4, 5, 6</td></tr> <tr><td>Mode of Action</td><td>6</td></tr> <tr><td>Safety</td><td>6, 7</td></tr> <tr><td>Precautions</td><td>7, 8</td></tr> <tr><td>Environmental Safety</td><td>8</td></tr> <tr><td>Note to User</td><td>9</td></tr> <tr><td>Package Information</td><td>9, 10</td></tr> </table>	Description	Page	Indications	2	Dosage	2	Administration	3, 4	Suggested Parasite Control Program	4, 5, 6	Mode of Action	6	Safety	6, 7	Precautions	7, 8	Environmental Safety	8	Note to User	9	Package Information	9, 10	<p>Introduction Privernectin™ Equine Oral Liquid (ivermectin) for Horses has been formulated for administration by oral drench. One low-volume dose is effective against important internal parasites, including the arterial stages of <i>Strongylus vulgaris</i>, and bots.</p> <p>Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents. Its convenience, broad-spectrum efficacy and safety margin make Privernectin™ Equine Oral Liquid an ideal parasite control product for horses.</p> <p>Privernectin™ is a registered trademark of First Priority, Inc., Elgin, IL 60123-1146.</p> <p>Product Description: Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents, which are isolated from fermentation of <i>Streptomyces avermectilis</i>. Privernectin™ Equine Oral Liquid is a clear, ready-to-use solution with each mL containing 1%</p>
Description	Page																										
Indications	2																										
Dosage	2																										
Administration	3, 4																										
Suggested Parasite Control Program	4, 5, 6																										
Mode of Action	6																										
Safety	6, 7																										
Precautions	7, 8																										
Environmental Safety	8																										
Note to User	9																										
Package Information	9, 10																										
<p>Ivermectin (10 mg), 0.2 mL propylene glycol, 80 mg polysorbate 80, 9 mg sodium phosphate monobasic monohydrate, 1.3 mg sodium phosphate dibasic anhydrous, 1 mg butylated hydroxytoluene, 0.1 mg disodium edetate, 3% benzyl alcohol and purified water q.s. ad 100%</p> <p>Product Indications: Privernectin™ Equine Oral Liquid is indicated for the effective treatment and control of the following parasites or parasitic conditions in horses:</p> <p>Large Strongyles: <i>Strongylus vulgaris</i> (adults and arterial larval stages), <i>S. edentatus</i> (adults and tissue stages), <i>S. equinus</i> (adults).</p> <p>Tricostophorus spp. (adults).</p> <p>Small Strongyles - including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae). <i>Cylicostephanus</i> spp., <i>Cylicocyclus</i> spp., <i>Cylicostephanus</i> spp., <i>Cylicodactyophorus</i> spp.</p> <p>Pilworms (adults and fourth-stage larvae) <i>Oxyuris equi</i></p>	<p>Ascarids (adults and third- and fourth-stage larvae) <i>Parascaris equorum</i></p> <p>Hairworms (adults) <i>Trichostrongylus axei</i></p> <p>Large-mouth Stomach Worms (adults) <i>Habronema muscae</i></p> <p>Bots (oral and gastric stages) <i>Gastrophilus</i> spp.</p> <p>Lungworms (adults and fourth-stage larvae) <i>Dicyclocoelus arfieldi</i></p> <p>Intestinal Threadworms (adults) <i>Strongylus</i> sp.</p> <p>Summer Sores caused by <i>Habronema</i> and <i>Draeschia</i> spp. cutaneous third-stage larvae</p> <p>Dermatitis caused by neck threadworm microfilariae, <i>Onchocerca</i> sp.</p> <p>Dosage, Privernectin™ Equine Oral Liquid for Horses is formulated for administration by oral drench. The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) of bodyweight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.</p>	<p>Administration: Use a calibrated dosing syringe inserted into the bottle to measure the appropriate dose, or pour the Privernectin™ Equine Oral Liquid into a graduated cylinder for dose measurement. Use a clean syringe if accessing the bottle to avoid contaminating the remaining product.</p> <p>Administration by drench: For administration by oral drench, use of an undiluted dose is recommended. Clear the horse's mouth of any food material, elevate the horse's head, and using a syringe, deposit the appropriate dose in the back of the mouth. In order to avoid unnecessary coughing or the potential for material to enter the trachea and lungs, do not use excessive pressure (squirting), do not use a large (diluted) dose volume, and do not deposit the dose in the laryngeal area. Increased dose rejection may occur if the dose is deposited in the buccal space. Keep the horse's head elevated and observe the horse to insure the dose is retained.</p>	<p>Suggested Parasite Control Program: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs.</p> <p>Privernectin™ Equine Oral Liquid effectively controls gastrointestinal nematodes and bots in horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by <i>S. vulgaris</i>. With its broad spectrum, Privernectin™ Equine Oral Liquid is well suited to be the major product in a parasite control program.</p> <p>Mode of Action: Ivermectin, one of the avermectins, kills certain parasitic roundworms and ectoparasites such as mites and lice. The avermectins are different in their action from other 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.</p>	<p>This chemical, a neurotransmitter, is called gammaaminobutyric 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.</p> <p>The enhancement of the GABA effect in arthropods such as mites and lice 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> <p>The principle 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>Safety: Privernectin™ Equine Oral Liquid may be used in horses of all ages including mares at any stage of pregnancy. Stallions may be treated</p>	<p>without adversely affecting their fertility. These horses have been treated with no adverse effects other than those noted under Note to User.</p> <p>Precautions • Caution Privernectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. • Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. Keep this and all drugs out of the reach of children. • Store in a tightly closed container at room temperature (between 15° - 30°C, 59° - 86°F). • Protect Privernectin™ Equine Oral Liquid from light.</p> <p>For customer service, contact First Priority, Inc. 1585 Todd Farm Drive Elgin, IL 60123-1146 1-800-650-4899</p>																						

NDC 0980-094-01


INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of respiratory, gastrointestinal and parasitic diseases. Ivermectin™ Equine Oral Liquid is indicated for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and numerous protozoans.

RECOMMENDED DOSE: 200 mcg of ivermectin per kilogram (91 mcg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.

How to Use: See 15-02

CAUTION: See 15-02

NO VARNISH



ivermectin™
Equine Oral Liquid
(ivermectin)
Liquid for Horses - 10 mg per mL
For Veterinary Use Only

For Animal Use Only • Keep Out of Reach of Children
Net Content: 500 mL
ANADA 250-251, Approved by FDA

PRECAUTIONS:

WARNING: Do not use in horses intended for food purposes.

CAUTION: Ivermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animals species or where adverse reactions, including fatalities in dogs, may occur. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

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

STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Ivermectin™ Equine Oral Liquid 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 contaminate lakes, streams, or ground water by direct application or by improper disposal of drug containers. Dispose of drug container in an approved landfill or by incineration.

Note to User: Swelling and itching reactions after treatment with Ivermectin™ Equine Oral Liquid have occurred in horses carrying heavy infections of neck threadworm microfilariae, *Onchocerca* sp. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur.

Healing of summer sores involving extensive tissue changes may require other therapy in conjunction with Ivermectin™ Equine Oral

Liquid. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

Package Information: Ivermectin™ Equine Oral Liquid is available in 100 mL, 200 mL, 500 mL, and 960 mL (32.46 fl. oz.) plastic bottles. Each bottle contains sufficient Ivermectin to treat 500 kg (1100 lb) horses as follows:

100 mL	10-500 kg (1100 lb) horses
200 mL	20-500 kg (1100 lb) horses
500 mL	50-500 kg (1100 lb) horses
960 mL	96-500 kg (1100 lb) horses

Contents may be poured into a graduated cylinder for dose measurement. Alternatively, a clean syringe may be inserted directly into the bottle to draw off the appropriate dose.



Priority Care
would you settle for less?
FIRST PRIORITY, INC.,
Elgin, IL 60123-1146, U.S.A.

PRECAUTIONS:

WARNING: Do not use in horses intended for food purposes.

CAUTION: Ivermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species or where adverse reactions, including fatalities in dogs, may occur. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

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

STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Ivermectin™ Equine Oral Liquid from light.

FOR VETERINARY USE ONLY

Ivermectin™
Equine Oral Liquid
(ivermectin)
Liquid for Horses - 10 mg per mL

Introduction	Page 2
Description	2
Indications	3, 4
Dosage	4
Administration	4, 5, 6
Suggested Parasite Control Program	6
Mode of Action	6, 7
Safety	7, 8
Precautions	8
Environmental Safety	9
Note to User	9, 10
Package Information	10

Introduction: Ivermectin™ Equine Oral Liquid (ivermectin) for Horses has been formulated for administration by oral drench. One low-volume dose is effective against important internal parasites, including the arthropod stages of *Strongylus vulgaris*, and bots.

Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents. Its convenience, broad-spectrum efficacy and safety margin make Ivermectin™ Equine Oral Liquid an ideal parasite control product for horses.

Ivermectin™ is a registered trademark of First Priority, Inc., Elgin, IL 60123-1146.

Product Description: Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents, which are isolated from fermentation of *Streptomyces avermitilis*. Ivermectin™ Equine Oral Liquid is a clear, ready-to-use solution with each mL containing 1%

ivermectin (10 mg), 0.2 mL propylene glycol, 80 mg polysorbate 80, 9 mg sodium phosphate monobasic monohydrate, 1.3 mg sodium phosphate dibasic anhydrous, 1 mg butylated hydroxytoluene, 0.1 mg disodium edetate, 3% benzyl alcohol and purified water q.s. ad 100%.

Product Indications: Ivermectin™ Equine Oral Liquid is indicated for the effective treatment and control of the following parasites or parasitic conditions in horses:

Large Strongyles: *Strongylus vulgaris* (adults and arthropod stages), *S. edentatus* (adults and tissue stages), *S. equinus* (adults), *Triodontophorus* spp. (adults).

Small Strongyles - including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae) *Cyathostomum* spp., *Cylicodontophorus* spp., *Cylicodontophorus* spp.

Pinworms (adults and fourth-stage larvae) *Oxyuris equi*

Ascarids (adults and third- and fourth-stage larvae) *Parascaris equorum*

Hairworms (adults) *Trichostrongylus axei*

Large-mouth Stomach Worms (adults) *Habronema muscae*

Bots (oral and gastric stages) *Gastrophilus* spp.

Lungworms (adults and fourth-stage larvae) *Dictyocaulus immitis*

Intestinal Threadworms (adults) *Strongyloides westeri*

Summer Sores caused by *Habronema* and *Dracina* spp.

Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

Dosage: Ivermectin™ Equine Oral Liquid for Horses is formulated for administration by oral drench. The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) of bodyweight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.

Administration: Use a calibrated dosing syringe inserted into the bottle to measure the appropriate dose, or pour the Ivermectin™ Equine Oral Liquid into a graduated cylinder for dose measurement. Use a clean syringe if accessing the bottle to avoid contaminating the remaining product.

Administration by drench: For administration by oral drench, use of an undiluted dose is recommended. Clear the horse's mouth of any food material, elevate the horse's head, and using a syringe, deposit the appropriate dose in the back of the mouth. In order to avoid unnecessary coughing or the potential for material to enter the trachea and lungs, do not use excessive pressure (squirting); do not use a large (diluted) dose volume, and do not deposit the dose in the laryngeal area. Increased dose rejection may occur if the dose is deposited in the buccal space. Keep the horse's head elevated and observe the horse to insure the dose is retained.

Suggested Parasite Control Program: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. Ivermectin™ Equine Oral Liquid effectively controls gastrointestinal nematodes and bots in horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by *S. vulgaris*. With its broad spectrum, Ivermectin™ Equine Oral Liquid is well suited to be the major product in a parasite control program.

Mode of Action: Ivermectin, one of the avermectins, kills certain parasitic roundworms and ectoparasites such as mites and lice. The avermectins are different in their action from other 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 and lice 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.

The principle 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: Ivermectin™ Equine Oral Liquid may be used in horses of all ages including mares at any stage of pregnancy. Stallions may be treated

without adversely affecting their fertility. These horses have been treated with no adverse effects other than those noted under **Note to User**.

Precautions

- Caution Ivermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.
- Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. Keep this and all drugs out of the reach of children.
- Store in a tightly closed container at room temperature (between 15° - 30°C, 59° - 86°F).
- Protect Ivermectin™ Equine Oral Liquid from light.

For customer service, contact
First Priority, Inc.
1585 Todd Farm Drive
Elgin, IL 60123-1146
1-800-650-4890

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitosis. Ivermectin™ Equine Oral Liquid is indicated for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, lung-worms, stomach worms, bots, lung-worms, summer sores and cutaneous mites.

RECOMMENDED DOSE: 200 mcg of ivermectin per kilogram (91 mcg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 110 lb (50 kg) horse.

See package insert for complete indications and use directions.

Reference No. OMS10PC Iss. 12-08
Exp. Date

NO VARNISH

For Animal Use Only • Keep Out of Reach of Children
Net Contents: 500 mL
ANADA 250-581, Approved by FDA

Priority Care
Ivermectin™
Equine Oral Liquid
(ivermectin)
Liquid for Horses - 10 mg per mL
For Veterinary Use Only

PRECAUTIONS:
WARNING: Do not use in horses intended for food purposes.

CAUTION: Ivermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

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

STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Ivermectin™ Equine Oral Liquid from light.

<p>Environmental Safety. Studies indicate that when ivermectin comes in contact with the soil, it readily and lightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain water-borne organisms on which they feed. Do not contaminate lakes, streams, or ground water by direct application or by improper disposal of drug containers. Dispose of drug container in an approved landfill or by incineration.</p> <p>Note to User: Swelling and itching reactions after treatment with Ivermectin™ Equine Oral Liquid have occurred in horses carrying heavy infections of neck threadworm microfilariae, <i>Onchocerca</i> sp. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur.</p> <p>Healing of summer sores involving extensive tissue changes may require other therapy in conjunction with Ivermectin™ Equine Oral</p>	<p>Liquid. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.</p> <p>Package Information: Ivermectin™ Equine Oral Liquid is available in 100 mL, 200 mL, 500 mL, and 950 mL (32.46 fl. oz.) plastic bottles. Each bottle contains sufficient ivermectin to treat 500 kg (1100 lb) horses as follows:</p> <p>100 mL 10-500 kg (1100 lb) horses 200 mL 20-500 kg (1100 lb) horses 500 mL 50-500 kg (1100 lb) horses 950 mL 95-500 kg (1100 lb) horses</p> <p>Contents may be poured into a graduated cylinder for dose measurement. Alternatively, a clean syringe may be inserted directly into the bottle to draw off the appropriate dose.</p>	<p>Priority Care would you settle for less? FIRST PRIORITY, INC., Egin, IL 60123-1146, U.S.A.</p>	<p>PRECAUTIONS: WARNING: Do not use in horses intended for food purposes.</p> <p>CAUTION: Ivermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.</p> <p>Keep this and all drugs out of the reach of children.</p> <p>STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Ivermectin™ Equine Oral Liquid from light.</p>	<p>FOR VETERINARY USE ONLY</p> <p>Ivermectin™ Equine Oral Liquid (ivermectin) Liquid for Horses - 10 mg per mL</p> <table border="0"> <tr><td>Introduction</td><td>Page</td></tr> <tr><td>Description</td><td>2</td></tr> <tr><td>Indications</td><td>3, 4</td></tr> <tr><td>Dosage</td><td>4</td></tr> <tr><td>Administration</td><td>4, 5, 6</td></tr> <tr><td>Suggested Parasite Control Program</td><td>6</td></tr> <tr><td>Mode of Action</td><td>6, 7</td></tr> <tr><td>Safety</td><td>7, 8</td></tr> <tr><td>Precautions</td><td>8</td></tr> <tr><td>Environmental Safety</td><td>9</td></tr> <tr><td>Note to User</td><td>9, 10</td></tr> <tr><td>Package Information</td><td>10</td></tr> </table>	Introduction	Page	Description	2	Indications	3, 4	Dosage	4	Administration	4, 5, 6	Suggested Parasite Control Program	6	Mode of Action	6, 7	Safety	7, 8	Precautions	8	Environmental Safety	9	Note to User	9, 10	Package Information	10	<p>Introduction Ivermectin™ Equine Oral Liquid (ivermectin) for Horses has been formulated for administration by oral drench. One low-volume dose is effective against important internal parasites, including the arterial stages of <i>Strongylus vulgaris</i>, and bots.</p> <p>Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents. Its convenience, broad-spectrum efficacy and safety margin make Ivermectin™ Equine Oral Liquid an ideal parasite control product for horses.</p> <p>Ivermectin™ is a registered trademark of First Priority, Inc., Egin, IL 60123-1146.</p> <p>Product Description: Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents, which are isolated from fermentation of <i>Streptomyces avermitilis</i>. Ivermectin™ Equine Oral Liquid is a clear, ready-to-use solution with each mL containing 1%.</p>
Introduction	Page																												
Description	2																												
Indications	3, 4																												
Dosage	4																												
Administration	4, 5, 6																												
Suggested Parasite Control Program	6																												
Mode of Action	6, 7																												
Safety	7, 8																												
Precautions	8																												
Environmental Safety	9																												
Note to User	9, 10																												
Package Information	10																												
<p>ivermectin (10 mg), 0.2 mL propylene glycol, 80 mg polysorbate 80, 9 mg sodium phosphate monobasic monohydrate, 1.3 mg sodium phosphate dibasic anhydrous, 1 mg butylated hydroxytoluene, 0.1 mg disodium edetate, 3% benzyl alcohol and purified water q.s. ad 100%</p> <p>Product Indications: Ivermectin™ Equine Oral Liquid is indicated for the effective treatment and control of the following parasites or parasitic conditions in horses:</p> <p>Large Strongyles: <i>Strongylus vulgaris</i> (adults and arterial larval stages), <i>S. edentatus</i> (adults and tissue stages), <i>S. equinus</i> (adults).</p> <p>Trichostrongylus spp. (adults)</p> <p>Small Strongyles - including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae) <i>Cyathostomum</i> spp., <i>Cylicocyclus</i> spp., <i>Cylicostephanus</i> spp., <i>Cylicodontophorus</i> spp.</p> <p>Pinworms (adults and fourth-stage larvae) <i>Oxyuris equi</i></p>	<p>Aascarids (adults and third- and fourth-stage larvae) <i>Parascaris equorum</i></p> <p>Hairworms (adults) <i>Trichostrongylus axei</i></p> <p>Large-mouth Stomach Worms (adults) <i>Habronema muscae</i></p> <p>Bots (oral and gastric stages) <i>Gastrophilus</i> spp.</p> <p>Lungworms (adults and fourth-stage larvae) <i>Diclyzocystus arnfieldi</i></p> <p>Intestinal Threadworms (adults) <i>Strongyloides westeri</i></p> <p>Summer Sores caused by <i>Habronema</i> and <i>Draschia</i> spp. cutaneous third-stage larvae.</p> <p>Dermatitis caused by neck threadworm microfilariae, <i>Onchocerca</i> sp.</p> <p>Dosage: Ivermectin™ Equine Oral Liquid for Horses is formulated for administration by oral drench. The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) of bodyweight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.</p>	<p>Administration: Use a calibrated dosing syringe inserted into the bottle to measure the appropriate dose, or pour the Ivermectin™ Equine Oral Liquid into a graduated cylinder for dose measurement. Use a clean syringe if accessing the bottle to avoid contaminating the remaining product.</p> <p>Administration by drench: For administration by oral drench, use of an unfluted dose is recommended. Clear the horse's mouth of any food material, elevate the horse's head, and using a syringe, deposit the appropriate dose in the back of the mouth. In order to avoid unnecessary coughing or the potential for material to enter the trachea and lungs, do not use excessive pressure (squirting), do not use a large (diluted) dose volume, and do not deposit the dose in the laryngeal area. Increased dose rejection may occur if the dose is deposited in the buccal space. Keep the horse's head elevated and observe the horse to insure the dose is retained.</p>	<p>Suggested Parasite Control Program: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated orally at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. Ivermectin™ Equine Oral Liquid effectively controls gastrointestinal nematodes and bots in horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by <i>S. vulgaris</i>. With its broad spectrum, Ivermectin™ Equine Oral Liquid is well suited to be the major product in a parasite control program.</p> <p>Mode of Action: Ivermectin, one of the avermectins, kills certain parasitic roundworms and ectoparasites such as mites and lice. The avermectins are different in their action from other 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.</p>	<p>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.</p> <p>The enhancement of the GABA effect in arthropods such as mites and lice 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> <p>The principle 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>Safety: Ivermectin™ Equine Oral Liquid may be used in horses of all ages including mares at any stage of pregnancy. Stallions may be treated</p>	<p>without adversely affecting their fertility. These horses have been treated with no adverse effects other than those noted under Note to User.</p> <p>Precautions</p> <ul style="list-style-type: none"> • Caution: Ivermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. • Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. Keep this and all drugs out of the reach of children. • Store in a tightly closed container at room temperature (between 15° - 30°C, 59° - 86°F). • Protect Ivermectin™ Equine Oral Liquid from light. <p>For customer service, contact: First Priority, Inc. 1685 Todd Farm Drive Egin, IL 60123-1146 1-800-650-8899</p>																								

NDC 5925-254-50

Priority
Care



**Privermectin™
Equine Oral Liquid**

(ivermectin)
Liquid for Horses - 10 mg per mL
For Veterinary Use Only

INDICATIONS: Control your veterinarian for anthelmintic in the diagnosis, treatment and control of parasitic. Privermectin™ Equine Oral Liquid is indicated for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), lungworms, bots, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis.

RECOMMENDED DOSE: 200 mcg of ivermectin per kilogram (0.45 mg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.

See package insert for complete indications and use directions.

PRECAUTIONS:

WARNING: Do not use in horses intended for food purposes.



Inv. 12-67

For Animal Use Only - Keep Out of Reach of Children
Net Contents: 500 mL (16.9 fl. oz.)

ANADA 200-221, Approved by FDA

CAUTION: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Protect from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

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

STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Privermectin™ Equine Oral Liquid from light.

LOT NO. EXP. DATE
NO VARNISH
Reader No. QM36PD

NDC 2822-004-01

Priority
Care



IvermectinTM
Equine Oral Liquid

(ivermectin)
Liquid for Horses - 10 mg per mL
For Veterinary Use Only

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitic infestations. Ivermectin Equine Oral Liquid is indicated for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, ascaridworms (roundworms), stomach threadworms, lungworms, summer sores, bots, lipworms, summer sores and cutaneous protozoans.

RECOMMENDED DOSE: 200 mcg of ivermectin per kilogram (2.2 pounds) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.

See package insert for complete instructions and use directions.

PRECAUTIONS:
Keep out of reach of children.

CAUTION: IvermectinTM Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as serious adverse reactions, including paralysis in dogs, may result. Keep out of smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

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

STORAGE: Store in a light resistant container between 15°-30°C (59°-87°F). Protect IvermectinTM Equine Oral Liquid from light.

LOT NO. EXP. DATE
NO VARNISH

For Animal Use Only - Keep Out of Reach of Children
Net Contents: 500 mL (16.9 fl. oz.)

No. 13-62

ANADA 200-921, Approved by FDA

Product No. 2822-004-01

NDC 28829-294-02

Priority
Care



**Privermectin™
Equine Oral Liquid**

(ivermectin)
Liquid for Horses - 10 mg per mL
For Veterinary Use Only

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Privermectin™ Equine Oral Liquid is indicated for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous anthelmintic.

RECOMMENDED DOSE: 200 mcg of ivermectin per kilogram (4.5 mg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat an 1100 lb (500 kg) horse.

See package insert for complete indications and use directions.

PRECAUTIONS:

Keep out of reach of children. Do not use in horses intended for food purposes.



Net. 12-02

CAUTION: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Keep out of reach of children and avoid contact with eyes.

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

STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Privermectin™ Equine Oral Liquid from light.

ORIG. EQ. USE
NO VARNISH
Resistor No. 0M28PC

For Animal Use Only • Keep Out of Reach of Children
Net Contents: 500 mL (16.9 FL. OZ.)

ANKOVA 800-521. Approved by FDA

NDC# 50629-204-05

Priority
Care



**Privermectin™
Equine Oral Liquid**

(Ivermectin)

Liquid for Horses - 10 mg per mL
For Veterinary Use Only

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Privermectin™ Equine Oral Liquid is indicated for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis.

RECOMMENDED DOSE: 200 mcg of ivermectin per kilogram (91 mcg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight; 10 mL will treat an 1100 lb (500 kg) horse.

See package insert for complete indications and use directions.

PRECAUTIONS:

WARNING: Do not use in horses intended for food purposes.



CAUTION: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

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

STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Privermectin™ Equine Oral Liquid from light.



Lot No. Exp. Date

NO VARNISH

For Animal Use Only • Keep Out of Reach of Children
Net Contents: 960 mL (32.46 fl. oz.)

Reorder No. OM063PC

Iss. 12-02

ANADA 200-321, Approved by FDA

NDC 5829-094-05

Priority
Care 

**Privermectin™
Equine Oral Liquid**

(ivermectin)
Liquid for Horses - 10 mg per mL
For Veterinary Use Only

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Privermectin™ Equine Oral Liquid is indicated for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis.

RECOMMENDED DOSE: 200 mcg of ivermectin per kilogram (91 mcg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight; 10 mL will treat an 1100 lb (500 kg) horse.

See package insert for complete indications and use directions.

PRECAUTIONS:

WARNING: Do not use in horses intended for food purposes.



CAUTION: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

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

STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Privermectin™ Equine Oral Liquid from light.

Lot No. Exp. Date

NO VARNISH

For Animal Use Only - Keep Out of Reach of Children

Net Contents: 900 mL (32.46 fl. oz.)

Reorder No. OM059PC

Iss. 12-02

ANADA 200-321, Approved by FDA

NDC# 58629-294-05

Priority
Care



**Privermectin™
Equine Oral Liquid**

(ivermectin)

Liquid for Horses - 10 mg per mL
For Veterinary Use Only

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Privermectin™ Equine Oral Liquid is indicated for the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis.

RECOMMENDED DOSE: 200 mcg of ivermectin per kilogram (91 mcg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight; 10 mL will treat an 1100 lb (500 kg) horse.

See package insert for complete indications and use directions.

PRECAUTIONS:

WARNING: Do not use in horses intended for food purposes.



CAUTION: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

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

STORAGE: Store in a tightly closed container between 15°-30°C (59°-86°F). Protect Privermectin™ Equine Oral Liquid from light.



Lot No. Exp. Date

NO VARNISH

For Animal Use Only • Keep Out of Reach of Children
Net Contents: 900 mL (32.48 fl. oz.)

Reorder No. 0M06SPC

Inc. 12-02

ANADA 800-321, Approved by FDA

ANADA 200-321, approved by FDA

FOR VETERINARY USE ONLY

Privermectin™ Equine Oral Liquid

(ivermectin)

Liquid for Horses - 10 mg per mL

Introduction

Privermectin™ Equine Oral Liquid (ivermectin) for Horses has been formulated for administration by oral drench. One low-volume dose is effective against important internal parasites, including the artemis stages of *Strongylus vulgaris*, and bots.

Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents. Its convenience, broad-spectrum efficacy and safety margin make Privermectin™ Equine Oral Liquid an ideal parasite control product for horses.

Privermectin™ is a registered trademark of First Priority, Inc., Elgin, IL 60123-1146

Product Description: Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents, which are isolated from fermentation of *Streptomyces avermitilis*. Privermectin™ Equine Oral Liquid is a clear, ready-to-use solution with each mL containing 1% ivermectin (10 mg), 0.2 mL propylene glycol, 80 mg polysorbate 80, 9 mg sodium phosphate monobasic monohydrate, 1.3 mg sodium phosphate dibasic anhydrous, 1 mg butylated hydroxytoluene, 0.1 mg disodium edetate, 3% benzyl alcohol and purified water q.s. ad 100%.

Product Indications: Privermectin™ Equine Oral Liquid is indicated for the effective treatment and control of the following parasites or parasitic conditions in horses.

Large Strongyles: *Strongylus vulgaris* (adults and arterial larval stages), *S. edentatus* (adults and tissue stages), *S. equinus* (adults), *Triodontophorus* spp (adults)

Small Strongyles - including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae):
Cyathostomum spp
Cylicocyclus spp
Cylicostephanus spp
Cylicodontophorus spp.

Pinworms (adults and fourth-stage larvae): *Oxyuris equi*

Ascarids (adults and third-and fourth-stage larvae): *Parascaris equorum*

Hairworms (adults): *Trichostrongylus axei*

Large-mouth Stomach Worms (adults): *Habronema muscae*

Bots (oral and gastric stages): *Gastrophilus* spp

Lungworms (adults and fourth-stage larvae): *Dictyocaulus imfieldi*

Intestinal Threadworms (adults): *Strongyloides westeri*

Summer Sores caused by *Habronema* and *Draschia* spp cutaneous third-stage larvae.

Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

Dosage: Privermectin™ Equine Oral Liquid for Horses is formulated for administration by oral drench. The recommended dose is 200 mcg of ivermectin per kilogram (100 mg per mL) of body weight.

stage larvae): *Dictyocaulus imfieldi*

Intestinal Threadworms (adults): *Strongyloides westeri*

Summer Sores caused by *Habronema* and *Draschia* spp cutaneous third-stage larvae.

Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

Dosage: Privermectin™ Equine Oral Liquid for Horses is formulated for administration by oral drench. The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight; 10 mL will treat an 1100 lb (500 kg) horse.

Administration: Use a calibrated dosing syringe inserted into the bottle to measure the appropriate dose, or pour the Privermectin™ Equine Oral Liquid into a graduated cylinder for dose measurement. Use a clean syringe if accessing the bottle to avoid contaminating the remaining product.

Administration by drench: For administration by oral drench, use of an undiluted dose is recommended. Clear the horse's mouth of any food material, elevate the horse's head, and using a syringe, deposit the appropriate dose in the back of the mouth. In order to avoid unnecessary coughing or the potential for material to enter the trachea and lungs, do not use excessive pressure (squirting), do not use a large (diluted) dose volume, and do not deposit the dose in the laryngeal area. Increased dose rejection may occur if the dose is deposited in the buccal space. Keep the horse's head elevated and observe the horse to insure the dose is retained.

Suggested Parasite Control Program: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. Privermectin™ Equine Oral Liquid effectively controls gastrointestinal nematodes and bots in horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by *S. vulgaris*. With its broad spectrum, Privermectin™ Equine Oral Liquid is well suited to be the major product in a parasite control program.

Mode of Action: Ivermectin, one of the avermectins, kills certain parasitic roundworms and ectoparasites such as mites and lice. The avermectins are different in their action from other 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 gammaaminobutyric 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 and lice 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.

The principle 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: Privermectin™ Equine Oral Liquid may be used in horses of all ages including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility. These horses have been treated with no adverse effects other than those noted under **Note to User**.

Precautions

- **Caution:** Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.
- Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.
- **Keep this and all drugs out of the reach of children.**
- Store in a tightly closed container at room temperature (between 15°-30°C, 59°-86°F).
- Protect Privermectin™ Equine Oral Liquid from light.

For customer service, contact **First Priority, Inc.**
1585 Todd Farm Drive
Elgin, IL 60123-1146
1-800-650-4899

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 contaminate lakes, streams, or ground water by direct application or by improper disposal of drug containers. Dispose of drug container in an approved landfill or by incineration.

Note to User:

Swelling and itching reactions after treatment with Privermectin™ Equine Oral Liquid have occurred in horses carrying heavy infections of neck threadworm microfilariae, *Onchocerca* sp. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur.

Healing of summer sores involving extensive tissue changes may require other therapy in conjunction with Privermectin™ Equine Oral Liquid. Reinfestation, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

Package Information:

Privermectin™ Equine Oral Liquid is available in 100 mL, 200 mL, 500 mL and 960 mL (32.46 fl. oz.) plastic bottles. Each bottle contains sufficient ivermectin to treat 500 kg (1100 lb) horses as follows:

- 100 mL 10-500 kg (1100 lb) horses
- 200 mL 20-500 kg (1100 lb) horses
- 500 mL 50-500 kg (1100 lb) horses
- 960 mL 96-500 kg (1100 lb) horses

Contents may be poured into a graduated cylinder for dose measurement. Alternatively, a clean syringe may be inserted directly into the bottle to draw off the appropriate dose.

500 mL and 960 mL (32.46 fl. oz.) plastic bottles. Each bottle contains sufficient ivermectin to treat 500 kg (1100 lb) horses as follows:

- 100 mL 10-500 kg (1100 lb) horses
- 200 mL 20-500 kg (1100 lb) horses
- 500 mL 50-500 kg (1100 lb) horses
- 960 mL 96-500 kg (1100 lb) horses

Contents may be poured into a graduated cylinder for dose measurement. Alternatively, a clean syringe may be inserted directly into the bottle to draw off the appropriate dose.



Iss 12-02



...would you settle for less?

First Priority, Inc.,
1585 Todd Farm Drive,
Elgin, IL 60123-1146, U.S.A.



Privermectin™ Equine Oral Liquid

(ivermectin)
Liquid for Horses - 10 mg per mL

Manufactured by
First Priority, Inc.
1585 Todd Farm Drive,
Elgin, IL 60123-1146

WARNING: Do not use in horses intended for food purposes.

Caution: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. Keep this and all drugs out of the reach of children. Store in a tightly closed container at room temperature (between 15°-30°C, 59°-86°F). Protect Privermectin™ Equine Oral Liquid from light.

PULL SLOWLY TO OPEN ▶



Privermectin™ Equine Oral Liquid

(ivermectin)
Liquid for Horses - 10 mg per mL

Manufactured by
First Priority, Inc.
1585 Todd Farm Drive,
Elgin, IL 60123-1146

WARNING: Do not use in horses intended for food purposes.

Caution: Privermectin™ Equine Oral Liquid has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. Keep this and all drugs out of the reach of children. Store in a tightly closed container at room temperature (between 15°-30°C, 59°-86°F). Protect Privermectin™ Equine Oral Liquid from light.

ANADA 200-321, approved by FDA

FOR VETERINARY USE ONLY

Privermectin™ Equine Oral Liquid

(ivermectin)

Liquid for Horses - 10 mg per mL

Introduction

Privermectin™ Equine Oral Liquid (ivermectin) for Horses has been formulated for administration by oral drench. One low-volume dose is effective against important internal parasites, including the arterial stages of *Strongylus vulgaris*, and bots.

Ivermectin is a potent antiparasitic agent whose chemical structure is different from those of other antiparasitic agents. Its convenience, broad-spectrum efficacy and safety margin make Privermectin™ Equine Oral Liquid an ideal parasite control product for horses.

Privermectin™ is a registered trademark of First Priority, Inc., Elgin, IL 60123-1146

Product Description: Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents, which are isolated from fermentation of *Streptomyces avermitilis*. Privermectin™ Equine Oral Liquid is a clear, ready-to-use solution with each mL containing 1% ivermectin (10 mg), 0.2 mL propylene glycol, 80 mg polysorbate 80, 9 mg sodium phosphate monobasic monohydrate, 1.3 mg sodium phosphate dibasic anhydrous, 1 mg butylated hydroxytoluene, 0.1 mg disodium edetate, 3% benzyl alcohol and purified water q.s. ad 100%.

Product Indications: Privermectin™ Equine Oral Liquid is indicated for the effective treatment and control of the following parasites or parasitic conditions in horses.

Large Strongyles: *Strongylus vulgaris* (adults and arterial larval stages), *S. edentatus* (adults and tissue stages), *S. equinus* (adults), *Triodontophorus* spp (adults)

Small Strongyles - including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae):
Cyathostomum spp
Cylicocyclus spp
Cylicostephanus spp
Cylicodontophorus spp.

Pinworms (adults and fourth-stage larvae): *Oxyuris equi*

Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*

Hairworms (adults): *Trichostrongylus axei*

Large-mouth Stomach Worms (adults): *Habronema muscae*

Bots (oral and gastric stages): *Gastrophilus* spp

Lungworms (adults and fourth-stage larvae): *Dictyocaulus imfieldi*

Intestinal Threadworms (adults): *Strongyloides westeri*

Summer Sores caused by *Habronema* and *Draschia* spp cutaneous third-stage larvae.

Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

Dosage: Privermectin™ Equine Oral Liquid for Horses is formulated for administration by oral drench. The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) of body weight.

stage larvae): *Dictyocaulus imfieldi*

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Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

Dosage: Privermectin™ Equine Oral Liquid for Horses is formulated for administration by oral drench. The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight; 10 mL will treat an 1100 lb (500 kg) horse.

Administration: Use a calibrated dosing syringe inserted into the bottle to measure the appropriate dose, or pour the Privermectin™ Equine Oral Liquid into a graduated cylinder for dose measurement. Use a clean syringe if accessing the bottle to avoid contaminating the remaining product.

Administration by drench: For administration by oral drench, use of an undiluted dose is recommended. Clear the horse's mouth of any food material, elevate the horse's head, and using a syringe, deposit the appropriate dose in the back of the mouth. In order to avoid unnecessary coughing or the potential for material to enter the trachea and lungs, do not use excessive pressure (squirting), do not use a large (diluted) dose volume, and do not deposit the dose in the laryngeal area. Increased dose rejection may occur if the dose is deposited in the buccal space. Keep the horse's head elevated and observe the horse to insure the dose is retained.

Suggested Parasite Control Program: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. Privermectin™ Equine Oral Liquid effectively controls gastrointestinal nematodes and bots in horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by *S. vulgaris*. With its broad spectrum, Privermectin™ Equine Oral Liquid is well suited to be the major product in a parasite control program.

Mode of Action: Ivermectin, one of the avermectins, kills certain parasitic roundworms and ectoparasites such as mites and lice. The avermectins are different in their action from other 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 gammaaminobutyric 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 and lice 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.

The principle 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: Privermectin™ Equine Oral Liquid may be used in horses of all ages including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility. These horses have been treated with no adverse effects other than those noted under **Note to User**.

Precautions

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- Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.
- **Keep this and all drugs out of the reach of children.**
- Store in a tightly closed container at room temperature (between 15°-30°C, 59°-86°F).
- Protect Privermectin™ Equine Oral Liquid from light.

For customer service, contact
First Priority, Inc.
1585 Todd Farm Drive
Elgin, IL 60123-1146
1-800-650-4899

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 contaminate lakes, streams, or ground water by direct application or by improper disposal of drug containers. Dispose of drug container in an approved landfill or by incineration.

Note to User:

Swelling and itching reactions after treatment with Privermectin™ Equine Oral Liquid have occurred in horses carrying heavy infections of neck threadworm microfilariae, *Onchocerca* sp. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur.

Healing of summer sores involving extensive tissue changes may require other therapy in conjunction with Privermectin™ Equine Oral Liquid. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

Package Information:

Privermectin™ Equine Oral Liquid is available in 100 mL, 200 mL, 500 mL and 960 mL (32.48 fl. oz.) plastic bottles. Each bottle contains sufficient ivermectin to treat 500 kg (1100 lb) horses as follows:

100 mL10-500 kg (1100 lb) horses
200 mL20-500 kg (1100 lb) horses
500 mL50-500 kg (1100 lb) horses
960 mL96-500 kg (1100 lb) horses

Contents may be poured into a graduated cylinder for dose measurement. Alternatively, a clean syringe may be inserted directly into the bottle to draw off the appropriate dose

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ISS 12-02

Priority
Care

...would you settle for less?

First Priority, Inc.,
1585 Todd Farm Drive,
Elgin, IL 60123-1146, U.S.A.

Priority
Care

Privermectin™
Equine Oral Liquid

(ivermectin)
Liquid for Horses - 10 mg per mL

Developed by:
First Priority, Inc.,
1585 Todd Farm Drive,
Elgin, IL 60123-1146

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PULL SLOWLY TO OPEN ▶

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