

FREEDOM OF INFORMATION (FOI) SUMMARY

Primectin™ (ivermectin) Liquid for Horses

ANADA 200-321

First Priority, Inc.

1585 Todd Farm Drive

Elgin, Il 60123-1 46

Date of Approval _____

1. GENERAL INFORMATION:

ANADA Number: 200-321

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

Generic Name: Ivermectin Liquid for Horses

Trade Name: Primectin™ Equine Oral Liquid

Marketing Status: RX

2. INDICATIONS FOR USE:

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 anchocerciasis

3. DOSAGE:

a. **DOSAGE FORM:** 100 mL Bottles

b. **ROUTE OF ADMINISTRATION:** For administration by stomach tube (nasogastric intubation) or as an oral drench.

c. **RECOMMENDED DOSAGES:** 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.

Each mL contains 1% (1 Omg) Ivermectin.

4. & 5. EFFECTIVENESS & ANIMAL SAFETY:

Under the provisions of the Federal Food, Drug and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (54 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (Eqvalan[®] Liquid for Horses). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of and ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that cannot quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based on the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study with Primectin[™] Equine Oral Liquid. The generic and pioneer products are solutions with the same active and inactive ingredients.

6. HUMAN SAFETY:

Human Food Safety

Horses: Not for use in horses intended for food.

Human Safety Relative to Possession, Handling and Administration:

The labeling contains adequate Warning statements as described below:
Refrain from smoking and eating when handling.
Wash hands after use. Avoid contact with eyes.
Keep this and all drugs out of reach of children.

7. **AGENCY CONCLUSION:**

This ANADA submitted under section 512(b) of the Federal Food, Drug and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that Primectin[™] Equine Oral Liquid when used under its proposed conditions of use, is safe and effective for its labeled indications.

8. **LABELING:**

Attachments: Generic and pioneer labeling

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

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

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.

BOTTLE LABEL

Indications: For the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascaris), 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.

Reorder No. 10M050PCARE Inv. 12-00
Lot No. Exp. Date

NDC 58820-294-10

Priority
Care 

**Primectin™ Equine Oral
Liquid (ivermectin)**

Liquid for Horses 10 mg per mL

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

Precautions:

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

CAUTION: Primectin™ 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.

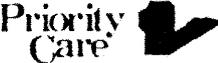
Store in a tightly closed container between 15°-30°C (59°-86°F).

OPEN HERE 

TAKE TIME 

OBSERVE LABEL DIRECTIONS

PACKAGE INSERT

<p>horses carrying heavy infections of neck throatworm microfilariae, <i>Onchocerca</i> sp. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable.</p> <p>Healing of summer sores involving extensive tissue changes may require other therapy in conjunction with Primectin™ Equine Oral Liquid. Re-infection, and measures for its prevention, should also be considered.</p> <p>Special consideration should be given to the effects or potential for injury from handling, restraint, and placement of the tube during administration by stomach tube.</p> <p>Primectin™ Equine Oral Liquid should be administered by drench if the risks associated with tubing are of concern. Due to the consequences of improper administration (also see Dosage and Administration), Primectin™ Equine Oral Liquid is intended for use by a veterinarian only and is not recommended for dispensing.</p> <p>Primectin™ Equine Oral Liquid in 1 to 20 and 1 to 40 dilutions with tap water has been shown to be stable for 72 hours under the conditions recommended for the product (i.e., at room temperature, in a tightly closed container, protected from light). The diluted product does not promote the growth of</p>	<p>common organisms. However, prolonged storage of the diluted product cannot be recommended, as the effects of possible contaminants and interactions with unlisted materials are unknown.</p> <p>Package Information Primectin™ Equine Oral Liquid is available in a 100 mL plastic bottle. Each bottle contains sufficient ivermectin to treat 10-500kg (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.</p> <div style="text-align: center; margin-top: 20px;">  <p>Priority Care</p> <p>would you settle for less?</p> <p>FIRST PRIORITY, INC. Egin, IL 60123-1146, U.S.A.</p> </div>	<p>Precautions:</p> <div style="border: 1px solid black; padding: 5px; text-align: center; margin: 10px 0;"> <p>WARNING: Do not use in horses intended for food purposes.</p> </div> <p>CAUTION: Primectin™ 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>Store in a tightly closed container between 15°-30°C (59°-86°F).</p> <div style="text-align: center; margin-top: 10px;"> <p>TAKE TIME  OBSERVE LABEL DIRECTIONS</p> </div>	<p style="text-align: center;">FOR VETERINARY USE ONLY</p> <hr/> <p style="text-align: center;">Primectin™ Equine Oral Liquid (ivermectin)</p> <hr/> <p style="text-align: center;">Liquid for Horses 18 mg per mL</p> <p style="text-align: center;">Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">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;">2</td> </tr> <tr> <td>Dosage</td> <td style="text-align: right;">3,4</td> </tr> <tr> <td>Administration</td> <td style="text-align: right;">4</td> </tr> <tr> <td>Suggested Parasite Control Program</td> <td style="text-align: right;">4,5</td> </tr> <tr> <td>Mode of Action</td> <td style="text-align: right;">5</td> </tr> <tr> <td>Safety</td> <td style="text-align: right;">6</td> </tr> <tr> <td>Precautions</td> <td style="text-align: right;">6,7</td> </tr> <tr> <td>Environmental Safety</td> <td style="text-align: right;">7</td> </tr> <tr> <td>Notes to Veterinarian</td> <td style="text-align: right;">7,8</td> </tr> <tr> <td>Package Information</td> <td style="text-align: right;">9</td> </tr> </table>	Introduction	Page	Description	2	Indications	2	Dosage	3,4	Administration	4	Suggested Parasite Control Program	4,5	Mode of Action	5	Safety	6	Precautions	6,7	Environmental Safety	7	Notes to Veterinarian	7,8	Package Information	9	<p>Introduction Primectin™ Equine Oral Liquid (ivermectin) for Horses has been formulated for professional administration by stomach tube or 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 Primectin™ Equine Oral Liquid an ideal parasite control product for horses.</p> <p>Primectin™ is a registered trademark of First Priority, Inc., Egin, IL 60123</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 avermectin</i>. Primectin™ 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%.</p>
Introduction	Page																											
Description	2																											
Indications	2																											
Dosage	3,4																											
Administration	4																											
Suggested Parasite Control Program	4,5																											
Mode of Action	5																											
Safety	6																											
Precautions	6,7																											
Environmental Safety	7																											
Notes to Veterinarian	7,8																											
Package Information	9																											
<p>27682 first priority primectin 133-2400 05/11/01 466 blk</p>																												
<p>Product Indications Primectin™ 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), <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>Pinnworms (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>Dictyocaulus immitis</i></p> <p>Intestinal Thresidworms (adults) <i>Strongylides westeri</i></p> <p>Summer Sores caused by <i>Habronema</i> and <i>Oeschia</i> spp. cutaneous third-stage larvae</p>	<p>Dermatitis caused by neck throatworm microfilariae, <i>Onchocerca</i> sp.</p> <p>Dosage Primectin™ Equine Oral Liquid for Horses is formulated for administration by stomach tube (nasogastric intubation) or as an 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 Primectin™ 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 stomach tube (gravity or positive flow): The recommended dose can be used undiluted or diluted up to 40 times with clean tepid water (see Notes to Veterinarian). Use tepid water to flush any drug remaining in the tube into the horse's stomach.</p> <p>Administration by drench: For administration by this method, an undiluted dose is usually preferred. 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</p>	<p>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 intensively at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Primectin™ 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, Primectin™ 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 arthropods 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 neurotrans-</p>	<p>mitter, 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 Primectin™ 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 Notes to Veterinarian.</p> <p>Precautions</p> <ul style="list-style-type: none"> - Caution: Primectin™ 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. 	<ul style="list-style-type: none"> • 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. • Protect Primectin™ Equine Oral Liquid (undiluted or diluted) from light. <p>For customer service, contact First Priority, Inc. 1585 Todd Farm Drive Egin, IL 60123 1-800-850-4899</p> <p>Environmental Safety Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain 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>Notes to Veterinarian Swelling and itching reactions after treatment with Primectin™ Equine Oral Liquid have occurred in</p>																								

Eqvalan (ivermectin)

worms except that nerve impulses are interrupted between the nerve ending and the muscle cell. Again, this leads to paralysis and death.

The principal peripheral neurotransmitter in mammals, acetylcholine, is unaffected by ivermectin. Ivermectin does not readily penetrate the central nervous system of mammals where GABA functions as a neurotransmitter.

Eqvalan (ivermectin)

Safety

EQVALAN® (ivermectin) 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 **Notes to Veterinarian**.

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

Eqvalan (ivermectin)

Precautions

- Caution: EQVALAN 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.
- Protect EQVALAN Liquid (undiluted or diluted) from light.

Eqvalan (ivermectin)

For customer service, contact Technical Services Department, U.S. Operations, Merck AgVet Division of Merck & Co., Inc. Box 2000, Rahway, New Jersey 07065-0915.

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.

Eqvalan (ivermectin)

Notes to Veterinarian

Swelling and itching reactions after treatment with EQVALAN have occurred in horses carrying heavy infections of neck threadworm microfilariae, *Onchocerca* s.p. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable.

Heating of summer sores involving extensive tissue changes may require other therapy in conjunction with EQVALAN. Reinfection, and measures for its prevention, should also be considered.

Special consideration should be given to the effects or potential for injury from handling, restraint, and placement of the tube during administration by stomach tube, EQVALAN Liquid should be administered by drench if the risks asso-

Eqvalan (ivermectin)

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 arnfieldi

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.

Eqvalan (ivermectin)

Dosage

EQVALAN Liquid for Horses is formulated for administration by stomach tube (nasogastric intubation) or as an 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 EQVALAN Liquid into a graduated cylinder for dose measurement. Use a clean syringe if accessing the bottle to avoid contaminating the remaining product.

Administration by stomach tube (gravity or positive flow): The recom-

Eqvalan (ivermectin)

mended dose can be used undiluted or diluted up to 40 times with clean tepid water (see Notes to Veterinarian). Use tepid water to flush any drug remaining in the tube into the horse's stomach.

Administration by drench: For administration by this method, an undiluted dose is usually preferred. 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 of 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.

Eqvalan (ivermectin)

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. EQVALAN 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, EQVALAN is well suited to be the major product in a parasite control program.

Eqvalan (ivermectin)

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 round-

Eqvalan (ivermectin)

warms except that nerve impulses are interrupted between the nerve ending and the muscle cell. Again, this leads to paralysis and death.

The principal peripheral neurotransmitter in mammals, acetylcholine, is unaffected by ivermectin. Ivermectin does not readily penetrate the central nervous system of mammals where GABA functions as a neurotransmitter.

Eqvalan (ivermectin)

	Page
Introduction	3
Description	
Indications	5, 6
Dosage	
Administration	7, 8
Suggested Parasite Control Program	9
Mode of Action	10, 11
Safety	12
Precautions	13
Environmental Safety	14
Notes to Veterinarian	15, 16
Package Information	17

Eqvalan (ivermectin)

Introduction

EQVALAN® (ivermectin) Liquid for Horses has been formulated for professional administration by stomach tube or oral drench. One low-volume dose is effective against important internal parasites, including the arterial stages of *Strongylus vulgaris*, and bots.

Discovered and developed by scientists from Merck Research Laboratories, 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 EQVALAN Liquid an ideal parasite control Product for horses.

EQVALAN is a registered trademark of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A.

Eqvalan (ivermectin)

Product Description

Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents, which are isolated from fermentation of *Streptomyces avermitilis*.

EQVALAN 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%.

Eqvalan (ivermectin)

Product indications

EQVALAN 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

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 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.

U.S. Pat 4,199,569 Made in U.S.A.
EQVALAN REG TM MERCK & CO., Inc.
8688303 Lot No & Exp Date ▼

FOR VETERINARY USE ONLY

Eqvalan®
(ivermectin)

Liquid for Horses
10 mg per mL

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

100 mL

Product 25877

Precautions:

WARNING: Do not use in horses intended for food purposes

CAUTION: EQVALAN® (ivermectin) 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. Protect EQVALAN Liquid (undiluted or diluted) from light.



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

10 mg per mL
Liquid for Horses
(ivermectin)
Eqvalan®
Product 25877 100 mL

Each mL contains 10 mg ivermectin, 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%.

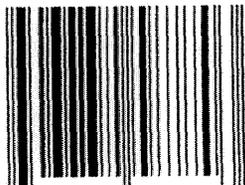
Precautions:

WARNING: Do not use in horses intended for food purposes

CAUTION: EQVALAN® (ivermectin) 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.



3 0373-258770 3

INDICATIONS:

EQVALAN® (ivermectin) Liquid provides effective control of the following parasites or parasitic conditions in horses: **Large Strongyles** — adults and arterial larval stages of *Strongylus vulgaris*, adults and tissue stages of *S. edentatus*, adults of *S. equinus* and *Triodontophorus* spp; **Small Strongyles** — including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae) — *Cyathostomum* spp, *Cylicocycylus* 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 arnfieldi*; **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.

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.

U.S. Pat 4,199,569
EQVALAN REG TM MERCK & CO., INC

Made in U.S.A.
83939

DOSAGE AND ADMINISTRATION:

EQVALAN® (ivermectin) Liquid for Horses is formulated for administration by stomach tube (nasogastric intubation) or as an 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 1 10 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

Store in a tightly closed container at room temperature. Protect EQVALAN Liquid (undiluted or diluted) from light.

Lot No & Exp Date ▼



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

FOR VETERINARY USE ONLY

Eqvalan®

(ivermectin)
Liquid for Horses
10 mg per mL

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

100 mL Product 25877

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

Product 25877

100 mL



CAUTION: EQVALAN® (ivermectin) 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. Protect EQVALAN Liquid (undiluted or diluted) from light.

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

Eqvalan®

(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.

Indications: For the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascaris), 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.
U.S. Pat. 4,199,569
EQVALAN REG TM MERCK & CO., Inc.
8688303

Lot No & Exp Date ▼
Made in U.S.A.

cc: HFV-199, ANADA 200-321 E0001
WFV-2 Special Mailing List
WFV-12 FOI Staff
HFV- 102 GADQC Reserve Copy
✓HFV-102 Green Book (NTurner)
HFA-305 Dockets Management Branch
HFR-CE650, CHI-DO
HFR-SW350, KAN-DO

ec: CVM Records\ONADE\A200321\E0001foi.sum