

Date of Approval: MAR - 8 2004

FREEDOM OF INFORMATION SUMMARY

**ORIGINAL ABBREVIATED NEW ANIMAL DRUG
APPLICATION (ANADA)**

ANADA 200-341

**SparMectin-E
(ivermectin)
10 mg/per mL**

Anthelmintic Suspension for Horses

**For the treatment and control of large strongyles, small strongyles,
hairworms, pinworms, roundworms (ascarids), intestinal threadworms,
largemouth stomach worms, bots, lungworms, summer sores, and cutaneous
onchocerciasis.**

Sponsored by:

**Veterinary Laboratories, Inc.
12340 Santa Fe Trail Drive
Lenexa, KS 66215**

<p>water by direct application or by improper disposal of drug containers. Dispose of drug container in approved landfill or by incineration</p> <p>Notes to Veterinarian Swelling and itching reactions after treatment with ivermectin 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. Healing of summer sores involving extensive tissue changes may require other therapy in conjunction with ivermectin. Reinfestation, and measures for its prevention, should also be considered</p> <p>13</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. Ivermectin 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), SparMectin-E Liquid is intended for use by a veterinarian only and is not recommended for dispensing. Ivermectin 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 common</p> <p>14</p>	<p>organisms. However, prolonged storage of the diluted product can not be recommended, as the effects of possible contaminants and interactions with untested materials are unknown.</p> <p>Package Information SparMectin-E Liquid for Horses is available in a 100 mL plastic bottle. Each bottle contains sufficient ivermectin to treat 10-500 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.</p> <p>ANADA 200-341, Approved by FDA Sparhawk-Veterinary Laboratories, Inc Lenexa, KS 66215, USA</p> <p>15</p>	<p>Precautions:</p> <p>RESIDUE WARNING: Do not use in horses intended for food purposes</p> <p>CAUTION: SparMectin-E (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.</p> <p>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 at room temperature between 15° and 30°C (59°-86°F). Protect SparMectin-E Liquid (undiluted or diluted) from light.</p> <p>1-6725-04 Rev. 9-02</p>
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<p>Bots (oral and gastric stages) <i>Gastrophilus</i> spp Lungworms (adults and fourth stage larvae) <i>Dictyocaulus arnfieldi</i> Intestinal Threadworms (adults). <i>Strongyloides westeri</i> Summer Sores caused by <i>Habronema</i> and <i>Draschia</i> spp cutaneous third-stage larvae Dermatitis caused by neck threadworm microfilariae, <i>Onchocerca</i> sp</p> <p>Dosage SparMectin-E Liquid for Horses is formulated for administration by stomach tube (nasogastric intubation) or as an oral drench. The recommended dose is 200 mcg</p> <p>5</p>	<p>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</p> <p>Administration Use a calibrated dosing syringe inserted into the bottle to measure the appropriate dose, or pour the SparMectin-E 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</p> <p>6</p>	<p>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 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</p> <p>7</p>	<p>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. SparMectin-E 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 is well suited to be the major product in a parasite control program</p> <p>8</p>
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<p>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</p> <p>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.</p> <p>See package insert for complete indications and use directions.</p> <p>Made in U.S.A. ANADA 200-341, Approved by FDA Sparhawk-Veterinary Laboratories, Inc Lenexa, KS 66215, USA</p> <p>Lot No Exp Date</p>	<p style="text-align: center;">SparMectin-E 10 mg/mL (Ivermectin)</p> <hr/> <p style="text-align: center;">Liquid for Horses</p> <hr/> <p style="text-align: center;">FOR VETERINARIAN USE ONLY</p> <p>Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p style="text-align: center;">NET CONTENTS: 100 mL</p> <p style="text-align: center;">SPARHAWK LABORATORIES, INC.</p>	<p>Precautions:</p> <p>RESIDUE WARNING: Do not use in horses intended for food purposes.</p> <p>CAUTION: SparMectin-E (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.</p> <p>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 at room temperature between 15° and 30°C (59°-86°F). Protect SparMectin-E Liquid (undiluted or diluted) from light.</p> <p>1-6725-04 Rev. 9-02</p> <p style="text-align: right;">OPEN HERE</p>
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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.

8698303

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
AgVet Division

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



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Lot No & Exp Date ▼

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.

DOSE AND ADMINISTRATION:
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(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

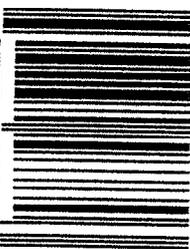
Product 25877

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:

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



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., *Cylicocyclus* spp., *Gylicostephanus* spp., *Cylicodon-tophorus* 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) — *Dielycocaulus arifolius*; Intestinal Threadworms (adults) — *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Daschia* 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

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

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-341
- b. Sponsor: Veterinary Laboratories, Inc.
12340 Santa Fe Trail Drive
Lenexa, KS 66215

Drug Labeler Code: 000857
- c. Established Name: Ivermectin
- d. Proprietary Name: SparMectin-E
- e. Dosage Form: Liquid
- f. How Supplied: 100 mL plastic bottles
- g. How Dispensed: Rx
- h. Amount of Active Ingredient: 10 milligrams of ivermectin per mL
- i. Route of Administration: Oral drench or stomach tube (nasogastric intubation)
- j. Species/Class: Horses
- k. Recommended Dosage: 200 micrograms per kilogram of body weight as a single dose
- l. Pharmacological Category: Anthelmintic
- m. Indications: For the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, largemouth stomach worms, bots, lungworms, summer sores, and cutaneous onchocerciasis.
- n. Pioneer Product: EQVALAN; ivermectin;
NADA 140-439; Merial Ltd.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new

animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Veterinary Laboratories, Inc. was granted a waiver from the requirements for an *in vivo* bioequivalence study for the generic product, SparMectin-E, on October 1, 1999. The generic product is administered as an oral liquid, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product EQVALAN, NADA 140-439, was approved on September 8, 1987.

3. **HUMAN SAFETY:**

This drug is indicated for use only in horses, which are non-food animals. Because this generic animal drug is not intended for food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Human food safety and human exposure warning statements are provided on the product label as follows: **“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.” “Do not use in horses intended for food purposes.”**

4. **AGENCY CONCLUSIONS:**

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that SparMectin-E, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. **ATTACHMENTS:**

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Generic Labeling for ANADA 200-341:

SparMectin-E, 10 mg ivermectin per mL

100 mL container label with accompanying package insert.

Pioneer Labeling for NADA 140-439:

Merial Ltd.'s EQVALAN, 10 mg ivermectin per mL.

100 mL container label with accompanying package insert.

<p>water by direct application or by improper disposal of drug containers. Dispose of drug container in approved landfill or by incineration</p> <p>Notes to Veterinarian Swelling and itching reactions after treatment with ivermectin 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. Healing of summer sores involving extensive tissue changes may require other therapy in conjunction with ivermectin. Reinfection, and measures for its prevention, should also be considered.</p> <p>13</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. Ivermectin 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), SparMectin-E Liquid is intended for use by a veterinarian only and is not recommended for dispensing. Ivermectin 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 common</p> <p>14</p>	<p>organisms. However, prolonged storage of the diluted product can not be recommended, as the effects of possible contaminants and interactions with untested materials are unknown.</p> <p>Package Information SparMectin-E Liquid for Horses is available in a 100 mL plastic bottle. Each bottle contains sufficient ivermectin to treat 10-500 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.</p> <p>ANADA 200-341, Approved by FDA Sparhawk-Veterinary Laboratories, Inc Lenexa, KS 66215, USA</p> <p>15</p>	<p>Precautions:</p> <p>RESIDUE WARNING: Do not use in horses intended for food purposes</p> <p>CAUTION: SparMectin-E (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.</p> <p>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 at room temperature between 15° and 30°C (59°-86°F). Protect SparMectin-E Liquid (undiluted or diluted) from light.</p> <p>1-5725-04 Rev. 9-02</p>	<p>Introduction Description Indications Dosage Administration Suggested Parasite Control Program Mode of Action Safety Precautions Environmental Safety Notes to Veterinarian Package Information</p> <p>1</p>
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<p>Bots (oral and gastric stages): <i>Gastrophilus</i> spp Lungworms (adults and fourth stage larvae): <i>Dictyocaulus immitis</i> Intestinal Threadworms (adults): <i>Strongyloides westeri</i> Summer Sores caused by <i>Habronema</i> and <i>Draschia</i> spp cutaneous third-stage larvae. Dermatitis caused by neck threadworm microfilariae, <i>Onchocerca</i> sp.</p> <p>Dosage SparMectin-E Liquid for Horses is formulated for administration by stomach tube (nasogastric intubation) or as an oral drench. The recommended dose is 200 mcg</p> <p>5</p>	<p>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.</p> <p>Administration Use a calibrated dosing syringe inserted into the bottle to measure the appropriate dose, or pour the SparMectin-E 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</p> <p>6</p>	<p>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 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</p> <p>7</p>	<p>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. SparMectin-E 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 is well suited to be the major product in a parasite control program.</p> <p>8</p>	<p>Mode of Action Ivermectin, one of the avermectins, certain parasitic roundworms, ectoparasites such as mites and lice, and other antiparasitic agents. This involves a chemical that serves as a neurotransmitter, is called gamma-aminobutyric acid or GABA. In roundworms, ivermectin stimulates release of GABA from nerve endings, enhancing binding of GABA to receptors at nerve junctions, interrupting nerve impulses - paralyzing and killing the parasite. The enhancement of the GABA</p> <p>9</p>
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Made in U.S.A. ANADA 200-341, Approved by FDA
Sparhawk-Veterinary Laboratories, Inc
Lenexa, KS 66215, USA

Lot No Exp. Date

SparMectin-E

10 mg/mL

(Ivermectin)

Liquid for Horses

FOR VETERINARIAN 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



Precautions:

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1-5725-04 Rev. 9-02

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U.S. Pat. 4,199,569
EQVALAN REG TM MERCK & CO., Inc.
 8688303

Made in U.S.A.

Lot No & Exp Date ▼

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Liquid for Horses
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AgVet Division

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MERCK

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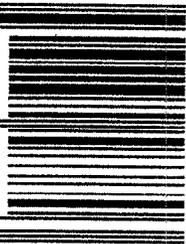
Each mL contains 10 mg ivermectin, 0.2 mL propylene glycol, 80 mg polysorbate 80, 9 mg sodium phosphate monobasic monohydrate, 1.3 mg sodium phosphate dibasic anhydrous, 1 mg butylated hydroxytoluene, 0.1 mg disodium edetate, 3% benzyl alcohol and purified water q.s. ad 100%.

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0373-258770

3

INDICATIONS:

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Made in U.S.A.
 83939

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

Eqvalan (ivermectin)

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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.

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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%.

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

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Eqvalan (ivermectin)

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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 thread-worm microfilariae, *Onchocerca* sp.

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-

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 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. 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.

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Eqvalan (ivermectin)

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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-

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.

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.

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.

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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.

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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* sp. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable.

Healing 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-

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Eqvalan (ivermectin)

ciated with tubing are of concern. Due to the consequences of improper administration (also see **Dosage and Administration**), EQVALAN Liquid is intended for use by a veterinarian only and is not recommended for dispensing.

EQVALAN 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 common organisms. However, prolonged storage of the diluted product cannot be recommended, as the effects of possible contaminants and interactions with untested materials are unknown.

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Eqvalan (ivermectin)

Package Information

EQVALAN Liquid for Horses (Product 25877) is available in a 100 mL plastic bottle. Each bottle contains sufficient ivermectin to treat 10–500 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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FOR VETERINARY USE ONLY

Eqvalan

(ivermectin)

Liquid for Horses

10 mcg/mL

MERCK
AGVET

Merck Company
Rahway, New Jersey 07065-0915

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