

SPARMECTIN E- ivermectin liquid
Sparhawk Laboratories, Inc.

SparMectin-E

(ivermectin)

Liquid for Horses

10 mg per mL

NOT FOR USE IN HUMANS

KEEP OUT OF REACH OF CHILDREN

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

INTRODUCTION

SparMectin-E (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.

PRODUCT DESCRIPTION

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

SparMectin-E 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, 0.54% w/v methyl paraben, 0.06% w/v propyl paraben and purified water q.s. ad 100%.

INDICATIONS

SparMectin-E (ivermectin) Liquid is indicated for the effective treatment and control of the following parasites in horses.

Large Strongyles (adults):

Strongylus vulgaris (also early forms in blood vessels)

Strongylus edentatus (also tissue stages)

Strongylus equinus

Triodontophorus spp. including:

Triodontophorus brevicauda

Triodontophorus serratus

Craterostomum acuticaudatum

Small Strongyles (adults, including those resistant to some benzimidazole class compounds):

Coronocyclus spp. including:

Coronocyclus coronatus

Coronocyclus labiatus

Coronocyclus labratus

Cyathostomum spp. including:

Cyathostomum catinatum

Cyathostomum pateratum

Cylicocyclus spp. including:

Cylicocyclus insigne

Cylicocyclus leptostomum

Cylicocyclus nassatus

Cylicocyclus brevicapsulatus

Cylicodontophorus spp.

Cylicostephanus spp. including:

Cylicostephanus calicatus

Cylicostephanus goldi

Cylicostephanus longibursatus

Cylicostephanus minutus

Petrovinema poculatum

Small Strongyles: Fourth-stage larvae

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

Roundworms or 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) - *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*

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.

DOSAGE

SparMectin-E Liquid for Horses is formulated for administration by stomach tube (nasogastric intubation) or as an oral drench. The recommended dose is 91 mcg of ivermectin per lb (200 mcg/kg) 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 SparMectin-E Liquid into a graduated cylinder for dose measurement. Use a clean syringe if accessing the bottle to avoid contaminating the remaining product.

Special consideration should be given to effects of potential for injury from handling, restraint, and placement of the stomach tube during administration of SparMectin-E Liquid. SparMectin-E Liquid should be administered by drench if the risks associated with tubing are of concern. Due to the potential consequences of improper administration, SparMectin-E Liquid is intended for use by a veterinarian only and is not recommended for dispensing.

SparMectin-E 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 contaminations and interactions with untested materials are unknown.

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. Use tepid water to flush any drug remaining in the tube into the horse's stomach.

Administration by drench: For administration of SparMectin-E by drench, 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 appropriated 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 horse's head elevated and observe the horse to insure the dose is retained.

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 (ivermectin) Liquid effectively controls gastrointestinal nematodes and bots in horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by *Strongylus vulgaris*.

PRODUCT ADVANTAGES Broad-spectrum Control

SparMectin-E Liquid kills important internal parasites, including bots and the arterial stages of *S. vulgaris*, with a single dose. SparMectin-E Liquid is a potent anti-parasitic agent that is neither a benzimidazole nor a organophosphate.

WARNINGS

Not for use in humans. Keep this and all drugs out of the reach of children. **Do not use in horses intended for human consumption.** Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. The Safety Data Sheet (SDS) contains more detailed occupational safety information.

CONTACT INFORMATION

To report suspected adverse events, for technical assistance or to obtain a copy of the SDS, contact Sparhawk Laboratories Inc at 1-800-255-6388 or 1-913-888-7500. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

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.

ENVIRONMENTAL SAFETY

Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of drug container in an approved landfill or by incineration.

INFORMATION FOR HORSE OWNERS

Owners should be advised of the potential that swelling and itching reactions may occur after treatment with SparMectin-E Liquid in horses carrying heavy infections of neck threadworm microfilarie, *Onchocerca sp.* These reactions are most likely the result of microfilarie dying in large numbers. Symptomatic treatment may be advisable.

Healing of summer sores involving extensive tissue changes may require other therapy in conjunction with SparMectin-E Liquid. Reinfection, and measures for its prevention, should also be considered.

Owners should be advised to consult their veterinarian if these conditions do not improve.

CLINICAL PHARMACOLOGY

Mode of Action: Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

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

ANIMAL SAFETY

SparMectin-E 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.

STORAGE INFORMATION

Store in a tightly closed container refrigerated between 2°C and 8°C (36°F and 46°F) with excursions up to 25°C (77°F) allowed. Protect SparMectin-E Liquid (undiluted or diluted) from light.

HOW SUPPLIED

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 measurements. Alternatively, a clean syringe may be inserted directly into the bottle to draw off the appropriate dose.

INDICATIONS: For the Effective Treatment and Control of Large Strongyles, Small Strongyles, Hairworms, Pinworms, Roundworms (ascaris), Intestinal Threadworms, Large-mouth Stomach Worms, Eets, Lungworms, Summer Sores and Cutaneous Onchocerciasis.

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

See package insert for complete indications and use directions.

Sparhawk Laboratories, Inc. Made in U.S.A.
Lenexa, KS 66215, USA

Approved by FDA under ANADA # 200-341

LOT NO.: EXP. DATE:

SparMectin-E[®] (ivermectin)

Liquid for Horses 10 mg per mL

**NOT FOR USE IN HUMANS
KEEP OUT OF REACH OF CHILDREN**

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

NET CONTENTS: 100 mL



MANUFACTURED BY LABORATORIES, INC. LENEXA, KS 66215 USA

WARNING: Not for use in humans. Keep this and all drugs out of the reach of children. Do not use in horses intended for human consumption. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

PRECAUTIONS: 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.

STORAGE INFORMATION: Store in a tightly closed container refrigerated between 2°C and 8°C (36°F and 46°F) with excursions up to 25°C (77°F) allowed. Protect SparMectin-E Liquid (undiluted or diluted) from light.

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1-8726-04

Rev. 03-23



<p>INTRODUCTION SparMectin-E (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 <i>Strongylus vulgaris</i>, and bots.</p> <p>NOT FOR USE IN HUMANS</p> <p>KEEP OUT OF REACH OF CHILDREN</p> <p>Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>PRODUCT DESCRIPTION Ivermectin is derived from the avermectins, a family of potent, broad-spectrum anti-parasitic agents, which are isolated from fermentation of <i>Streptomyces avermitilis</i>.</p> <p style="text-align: center;">1</p>	<p>SparMectin-E 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 anhydrous, 1.3 mg sodium phosphate dibasic anhydrous, 1 mg butylated hydroxytoluene, 0.1 mg disodium edetate, 0.54% w/v methyl paraben, 0.06% w/v propyl paraben and purified water q.s. ad 100%.</p> <p>INDICATIONS SparMectin-E (ivermectin) Liquid is indicated for the effective treatment and control of the following parasites in horses.</p> <p>Large Strongyles (adults): <i>Strongylus vulgaris</i> (also early forms in blood vessels); <i>Strongylus edentatus</i> (also tissue stages); <i>Strongylus equinus</i></p> <p style="text-align: center;">2</p>	<p><i>Tridontophorus</i> spp. including: <i>Tridontophorus brevicauda</i> <i>Tridontophorus serratus</i> <i>Craterostomum aciculicaudum</i></p> <p>Small Strongyles (adults, including those resistant to some benzimidazole class compounds): <i>Coronocylcus</i> spp. including: <i>Coronocylcus coronatus</i> <i>Coronocylcus labiatus</i> <i>Coronocylcus labrahus</i></p> <p><i>Cyathostomum</i> spp. including: <i>Cyathostomum catenatum</i> <i>Cyathostomum pateratum</i> <i>Cylicocylcus</i> spp. including: <i>Cylicocylcus insignis</i> <i>Cylicocylcus lepidostomum</i> <i>Cylicocylcus rissatus</i> <i>Cylicocylcus brevicapsulatus</i></p> <p style="text-align: center;">3</p>	<p><i>Cylicodontophorus</i> spp. <i>Cylicostephanus</i> spp. including: <i>Cylicostephanus calicatus</i> <i>Cylicostephanus goli</i> <i>Cylicostephanus longibursatus</i> <i>Cylicostephanus minutus</i> <i>Petrovinaema paculatum</i></p> <p>Small Strongyles: Fourth stage larvae Pinworms (adults and fourth-stage larvae) - <i>Oxyuris equi</i></p> <p>Roundworms or ascaris (adults and third- and fourth-stage larvae) - <i>Parascaris equorum</i> 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>Gasterophilus</i> spp. including <i>G. intestinalis</i> and <i>G. nasalis</i></p> <p>Lungworms (adults and fourth-stage larvae) - <i>Dicyocaulus immitis</i></p> <p style="text-align: center;">4</p>
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<p>repeated as appropriate. SparMectin-E (ivermectin) liquid effectively controls gastrointestinal nematodes and bots in horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by <i>Strongylus vulgaris</i>.</p> <p>PRODUCT ADVANTAGES Broad-spectrum Control - SparMectin-E Liquid kills important internal parasites, including bots and the arterial stages of <i>S. vulgaris</i>, with a single dose. SparMectin-E Liquid is a potent anti-parasitic agent that is neither a benzimidazole nor an organophosphate.</p> <p>WARNINGS Not for use in humans. Keep this and all drugs out of reach of children. Do not use in horses intended for human consumption. Refrain from smoking and eating when handling.</p> <p style="text-align: center;">9</p>	<p>Wash hands after use. Avoid contact with eyes. The Safety Data Sheet (SDS) contains more detailed occupational safety information.</p> <p>CONTACT INFORMATION: To report suspected adverse events, for technical assistance or to obtain a copy of the SDS, contact Sparhawk Laboratories, Inc. at 1-800-255-8388 or 1-913-888-7500. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimal</p> <p>PRECAUTIONS 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 style="text-align: center;">10</p>	<p>Environmental Safety Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of drug container in an approved landfill or by incineration.</p> <p>INFORMATION FOR HORSE OWNERS Owners should be advised of the potential that swelling and itching reactions may occur after treatment with SparMectin-E Liquid in horses carrying heavy infections of neck threadworm microfilariae, <i>Onchocerca</i> sp. These reactions are 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 SparMectin-E</p> <p style="text-align: center;">11</p>	<p>Liquid. Reinfection, and measures for its prevention, should also be considered.</p> <p>Owners should be advised to consult their veterinarian if these conditions do not improve.</p> <p>CLINICAL PHARMACOLOGY Mode of Action: Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also</p> <p style="text-align: center;">12</p>
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<p>interact with other ligand-gated chloride channels, such as those found in the neurotransmitter gamma-aminobutyric acid (GABA).</p> <p>The margin of safety is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.</p> <p>ANIMAL SAFETY SparMectin-E 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.</p> <p>STORAGE INFORMATION Store in a tightly closed container refrigerated between 2°C and 8°C (36°F and 46°F)</p> <p style="text-align: center;">13</p>	<p>with excursions up to 25°C (77°F) allowed. Protect SparMectin-E Liquid (undiluted or diluted) from light.</p> <p>HOW SUPPLIED 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>Made in U.S.A. Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA Approved by FDA under ANADA # 200-341</p> <p style="text-align: center;">14</p>	<p>WARNING: Not for use in humans. Keep this and all drugs out of the reach of children. Do not use in horses intended for human consumption. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.</p> <p>PRECAUTIONS: 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>STORAGE INFORMATION: Store in a tightly closed container refrigerated between 2°C and 8°C (36°F and 46°F) with excursions up to 25°C (77°F) allowed. Protect SparMectin-E Liquid (undiluted or diluted) from light.</p> <p>CONTACT INFORMATION: To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data sheet (SDS), contact Sparhawk Laboratories, Inc. at 1-800-255-8388 or 1-913-888-7500. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimal</p> <p>1-8726-04 Rev. 03-23</p>	<p>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 refection may occur if the dose is deposited in the buccal space. Keep horse's head elevated and observe the horse to insure the dose is retained.</p> <p>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</p> <p style="text-align: center;">8</p>
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<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; dermatitis caused by neck threadworm microfilariae, <i>Onchocerca</i> sp.</p> <p>DOSE SparMectin-E Liquid for Horses is formulated for administration by stomach tube (nasogastric intubation) or as an oral drench. The recommended dose is 91 mcg of ivermectin per lb (200 mcg/kg) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight. 10 mL will treat a 1100 lb (500 kg) horse.</p> <p>ADMINISTRATION Use a calibrated dosing syringe inserted into the bottle to measure the appropriate dose, or</p> <p style="text-align: center;">5</p>	<p>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>Special consideration should be given to the effects or potential for injury from handling, restraint, and placement of the stomach tube during administration of SparMectin-E Liquid. SparMectin-E Liquid should be administered by drench if the risks associated with tubing are of concern. Due to the potential consequences of improper administration, SparMectin-E Liquid is intended for use by a veterinarian only and is not recommended for dispensing.</p> <p>SparMectin-E 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</p> <p style="text-align: center;">6</p>	<p>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 contaminations and interactions with untested materials are unknown.</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 tapid water. Use tapid water to flush any drug remaining in the tube into the horse's stomach.</p> <p>Administration by drench: For administration of SparMectin-E Liquid by drench, an undiluted dose is recommended. Clear the horse's mouth of any food material, elevate</p> <p style="text-align: center;">7</p>	<p>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 contaminations and interactions with untested materials are unknown.</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 tapid water. Use tapid water to flush any drug remaining in the tube into the horse's stomach.</p> <p>Administration by drench: For administration of SparMectin-E Liquid by drench, an undiluted dose is recommended. Clear the horse's mouth of any food material, elevate</p> <p style="text-align: center;">7</p>
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SPARMECTIN E[®] ivermectin liquid

Product Information

Product Type

PRESCRIPTION ANIMAL DRUG

Item Code (Source)

NDC:58005-725

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	10 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58005-725-04	100 mL in 1 BOTTLE, PLASTIC		
2	NDC:58005-725-05	200 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200341	05/01/2014	

Labeler - Sparhawk Laboratories, Inc. (147979082)

Revised: 7/2023

Sparhawk Laboratories, Inc.