SUITABILITY PETITION

Petition Filed By:
Richdel, Inc.
23 Industrial Parkway
Moundhouse, NV 89706

Proposed Product:
Oral Gel Form of Solubilized Ivermectin for Horses

Date: May 22, 2003

SUITABILITY PETITION

The undersigned submits this petition under 512(n)(3) of the Federal Food, Drug, and Cosmetic Act, to request that the Commissioner of Food and Drugs permit Richdel, Inc. to file an abbreviated new animal drug application having a dosage form which differs from that of the listed approved new animal drug.

Name: Richard A. Merriner Date: 5/21/03

Title: President

I. Action Requested

The requested action is for the Commissioner to permit the filing of an abbreviated new animal drug application (ANADA) for our proposed product which differs from the approved pioneer product as follows:

Pioneer Product (Reference Drug)

Eqvalan® (ivermectin) Liquid (10 mg/mL), NADA 140-439, originally approved by the Center for Veterinary Medicine on 14 September 1987, and sponsored by Merial Ltd., is an oral liquid indicated for the treatment of large and small strongyles, pinworms, ascarids, hairworms, large-mouth stomach worms, bots, lungworms, intestinal threadworms, and dermatitis in horses. It is offered in an oral liquid formulation containing 10 mg per mL ivermectin. The liquid is administered via stomach tube or as a drench at a rate of 200 mcg ivermectin per kg (91 mcg/lb) body weight.

Proposed Product

The proposed product is an oral gel containing 1% (10 mg/g, w/w) solubilized ivermectin, which is indicated for use in horses for the same claims and will be administered at the same levels of ivermectin as the pioneer product. Syringes of the proposed gel are individually packaged with one syringe per box. Each syringe plunger increment will treat 110 lbs. of body weight, up to 1100 lbs.

II. Statement of Grounds

The legal basis under which this application proceeds is as promulgated in the FD&C Act which allows the Commissioner to accept a generic drug application for an animal drug product which differs in dosage form from the pioneer or reference drug product. The dosage form for the proposed generic product described in this petition is similar to that of the pioneer drug in that both products are oral dosage forms containing solubilized ivermectin. The difference is that this proposed generic product is in an oral gel whereas the pioneer drug is an oral liquid.

The petitioner is not aware of any information, which would be unfavorable to the granting of the requested action.

III. Environmental Impact

Richdel, Inc. hereby requests a categorical exclusion from the requirements of preparing an environmental assessment based on 21 CFR 25.30(h). This subparagraph provides for categorical exclusions for actions such as the issuance, amendment, or revocation of procedural or administrative regulations and guidelines, including procedures for submission of applications for product development, testing and investigational use, and approval. To the best of petitioner's knowledge, no extraordinary circumstances exist, which may significantly affect the human environment as discussed under 21 CFR 25.21.

IV. Economic Impact

An economic impact statement pertaining to (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand has not been prepared for this petition. Richdel will provide such an analysis if so requested by the Commissioner.

V. Identification of Single Listed Pioneer Drug

NADA NO.	NAME OF DRUG	COMPANY	APPROVAL DATE
140-439	Eqvalan® Liquid	Merial Ltd.	09/14/1987

VI. Labeling

The following pages provide copies of the proposed generic product labeling and the reference drug labeling. Differences between the proposed generic product labeling and the pioneer product labeling:

A. Box Front Panel

1. The NADA approval statement is changed to reflect ANADA approval, and in accordance with PPPM Guide 1240.4000, has been moved to the bottom of the panel.

2 Changed " EQVALAN®" to "Brand Name".

3. Changed "Liquid for Horses 10 mg per mL" to "Oral Gel for Horses 10 mg per gram"
4. Net contents statement is changed from 100 mL to 10 grams.
5. The sponsor logo is changed.

B. Box Side Panels

1. Left Panel: Name and address of sponsor is changed.

2. Right Panel: Bar code is different.

C. Box Back Panel

1. "EQVALAN®" and "Liquid" are changed throughout to "Brand Name" and "Oral Gel."
2. The directions for administration are changed to reflect administering the gel vs. the liquid.
3. The ingredients statement is changed from "Each mL contains..." to "Each gram contains..." In addition, though the pioneer label contains the name and amount of each inactive, this information has been omitted from the proposed gel label in accordance with 21 CFR 201.105.

D. Oral Gel Syringe Label vs. Liquid Bottle Label

1. "EQVALAN," "Liquid," and "10 mg per mL" are changed throughout to "Brand Name," "Oral Gel," and "10 mg per gram."
2. The sponsor's name and address are changed from Merial to Richdel, Inc.

3. Product number is changed.

4. On the side panel under Recommended Dose, "Each mL contains..." and "10 mg per mL..." are changed to "Each gram contains..." and "10 mg per gram..."

5. The second side panel is omitted from the proposed syringe label due to space constraints. The information contained in this panel is provided in the package insert. The second panel of the proposed syringe label directs reference to the package insert for complete indications, precautions, warnings, and use directions.

6. In accordance with PPPM Guide 1240.4000, the ANADA approval statement is added to the bottom of the main panel.

D. Package Insert

1. The NADA approval statement is changed to reflect ANADA approval.

2. "Eqvalan" and "Liquid for Horses 10 mg per mL" is changed throughout to "Brand Name" and "Oral Gel for Horses 10 mg per gram."

3. The first sentence in the Introduction omits reference to dosing by stomach tube or drench.

4. The first sentence of the second paragraph of Introduction omits reference to discovery and development of ivermectin by Merck.

5. The second paragraph of the Product Description is changed to describe the oral gel vs. the liquid. Also, the listing of inactive ingredients, though present on the pioneer label, is omitted from the proposed gel label in accordance with 21 CFR 201.105.

6. Under Dosage, reference to administration by stomach tube or drench is omitted and the dosage is change to reflect gram(s) of gel vs. mL of liquid.

7. Under Administration, the directions are changed to reflect adjustment of the syringe plunger and administration of the gel, vs. diluting the liquid and administering by stomach tube or drench.

8. Under Safety, the contact name and phone number for reporting adverse events or obtaining an MSDS are changed.

9. The statements under How Supplied are changed to reflect the gel syringe.

10. The copyright information and sponsor name and address are changed.

VII. 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 this petition.

Signature: 

Name of Petitioner: Richdel, Inc.

Mailing Address: 23 Industrial Parkway
Moundhouse, NV 89706

Telephone Number: (775) 246-3022

PROPOSED GENERIC DRUG LABELING

Syringe Label (Front Side)

FOR VETERINARY USE ONLY

BRANDNAME

(ivermectin)

Oral Gel for Horses

10 mg per gram

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

Product **12345**

10 grams

ANADA 200-XXX, Approved by the FDA

Syringe Label (Back Side)

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 gram contains sufficient ivermectin to treat 110 lb (50 kg) of body weight: 10 grams will treat an 1100 lb (500 kg) horse.

See package insert for complete indications, precautions, warnings and use directions.

Lot No. & Exp. Date

End of Box

10 grams

Product **12345**

BRANDNAME

(ivermectin)

Oral Gel for Horses

10 mg per gram

SEALED FOR
SECURITY.
IF BROKEN DO
NOT ACCEPT

Front of Box

FOR VETERINARY USE ONLY

BRANDNAME

(IVERMECTIN)

Oral Gel for Horses

10 mg per gram

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

10 grams

ANADA 200-XXX, Approved by the FDA

Left Side of Box

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 waterborne 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.

Lot No & Exp Date

Marketed by
Richdel, Inc.
Moundhouse, NV 89706

Right Side of Box

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

PRECAUTIONS

Store tightly capped container at room temperature. Protect BRANDNAME (ivermectin) Oral Gel from light.

Brandname Gel 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.

BAR CODE

Back of Box

INDICATIONS

BRANDNAME (ivermectin) Oral Gel 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 states 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, *Cylicostephanus* spp, Cylicodontophorus spp; **Pinworms** (adults and fourth-state larvae) – *Oxyuris equi*; **Ascarids** (adults and third- and fourth- state larvae) – *Parascaris equorum*; **Hairworm** (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.

DOSAGE AND ADMINISTRATION

Brandname Gel for Horses is formulated for oral administration. The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) of body weight. Each gram contains sufficient ivermectin to treat 100 lb (50 kg) of body weight; 10 grams will treat an 1100 lb (500 kg) horse.

See package insert for complete indications, precautions, warnings and use directions.

Each gram of gel contains 1% ivermectin (10 mg).

U.S. Pat. X,XXX,XXX

Product **12345**

BRANDNAME GEL is a registered trademark of Richdel

ANADA 200-XXX, Approved by the FDA
FOR VETERINARY USE ONLY

BRAND NAME
(Ivermectin)
Oral Gel for Horses

10 mg per gram

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

INTRODUCTION

BRANDNAME (ivermectin) Oral Gel for Horses has been formulated for professional administration. 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 Brandname Gel an ideal parasite control for horses.

PRODUCT DESCRIPTION

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

Brandname Gel is a clear yellow, ready-to-use gel with each gram containing 1% ivermectin (10 mg).

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 wide 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.

INDICATIONS

Brandname Gel 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 Strongylus - 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 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

Brandname Gel for Horses is formulated for oral administration. The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) of body weight. Each gram contains sufficient ivermectin to treat 110 lb. (50 kg) of body weight: 10 grams will treat an 1100 lb (500 kg) horse.

ADMINISTRATION

(1) While holding plunger, turn the knurled ring on the plunger ¼ turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking. (2) Lock the ring in place by making a ¼ turn to the right. (3) Make sure that the horse's mouth contains no feed. (4) Remove the cover from the tip of the syringe (5) Insert the syringe tip into the horses mouth at the space between the teeth. (6) Depress the plunger as far as it will go, depositing gel on the back of the tongue. (7) Immediately raise the horse's head for a few seconds after dosing.

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. Brandname Gel effectively controls gastrointestinal nematodes and bets in horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by *S. vulgaris.* With its broad spectrum, Brandname Gel is well suited to be the major product in a parasite control program.

SAFETY

Brandname Gel 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**.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Richdel at 1-800-648-0950.

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

PRECAUTIONS

- Brandname Gel 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 Brandname Gel 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.

NOTES TO VETERINARIAN

Swelling and itching reactions after treatment with Brandname Gel 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 Brandname Gel. Reinfection, and measures for its prevention, should also be considered.

HOW SUPPLIED

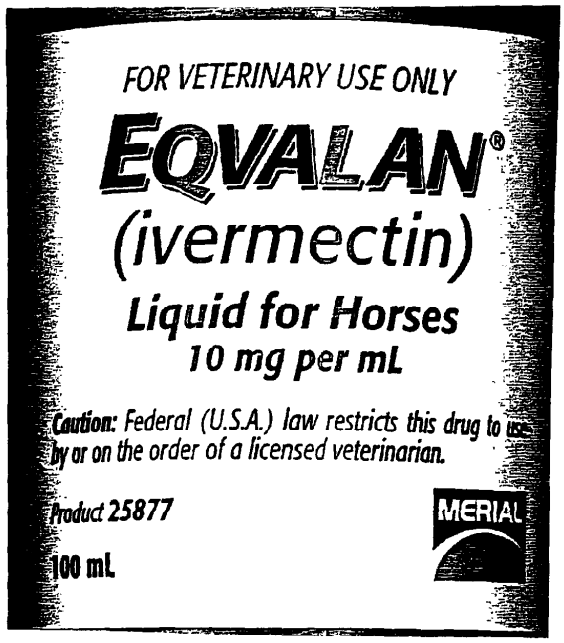
Brandname Gel for Horses (Product 12345) is available in a 10 gram plastic syringe. Each syringe contains sufficient ivermectin to treat 1-500 kg (1100 lb) horse.

Marketed by
Richdel, Inc.
Moundhouse, NV 89706

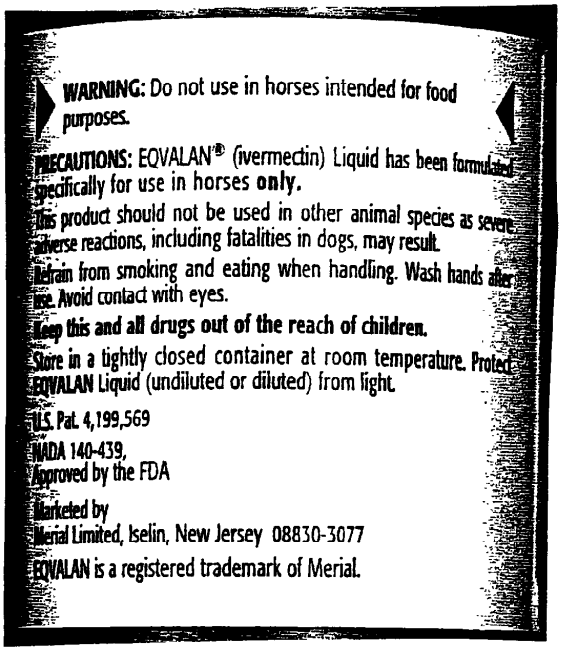
REFERENCE

DRUG LABELING

Bottle - Front



Bottle - Side



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

PRECAUTIONS: 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.

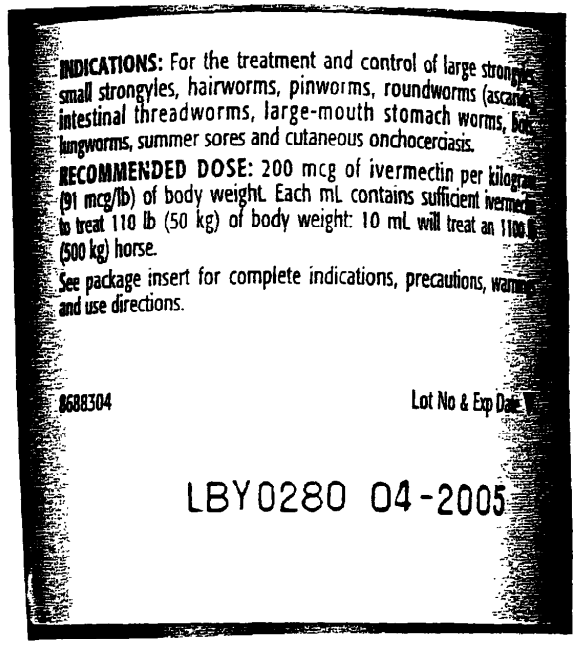
U.S. Pat. 4,199,569

NADA 140-439,
Approved by the FDA

Marketed by
Merial Limited, Iselin, New Jersey 08830-3077

EQVALAN is a registered trademark of Merial.

Bottle - Side


INDICATIONS: For the treatment and control of large stron
small strongyles, hairworms, pinworms, roundworms (asca
intestinal threadworms, large-mouth stomach worms, bo
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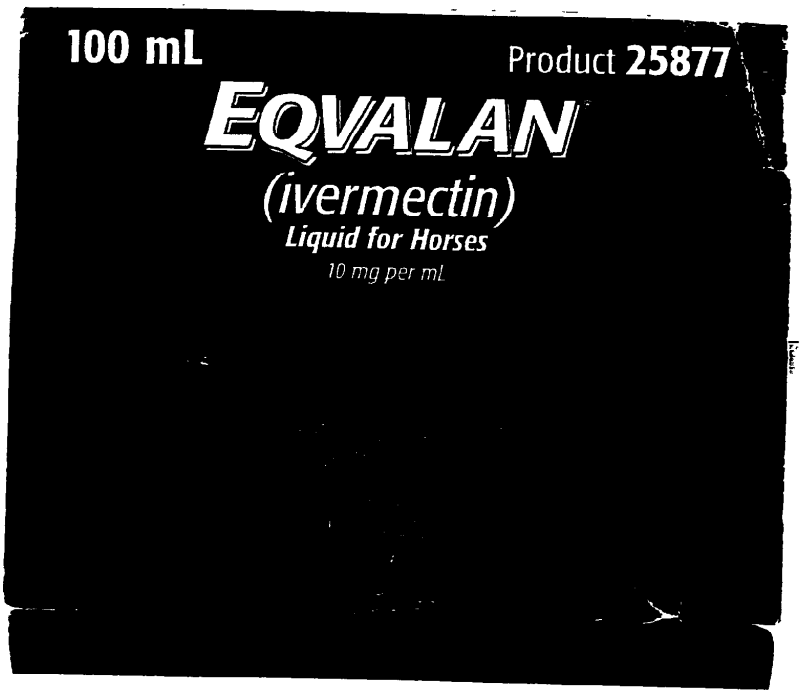
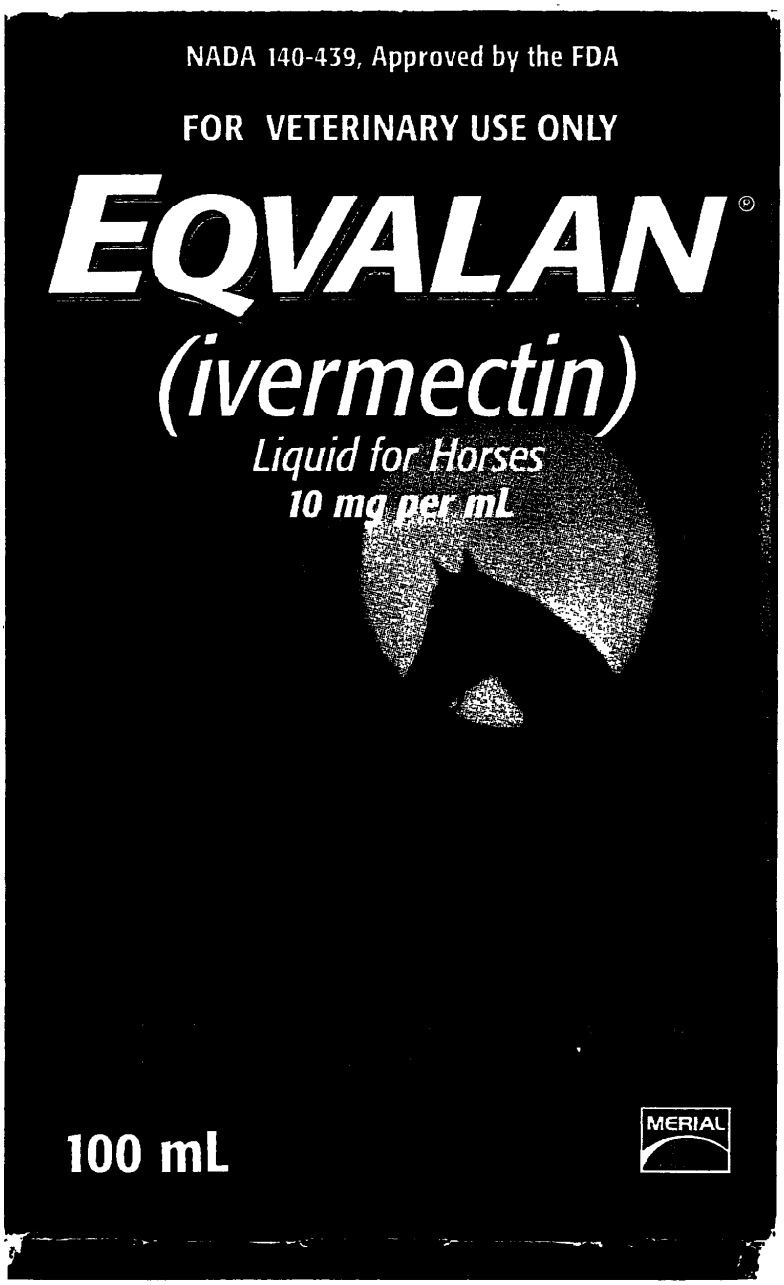
RECOMMENDED DOSE: 200 mcg of ivermectin per kilogra
(91 mcg/lb) of body weight. Each mL contains sufficient iverme
to treat 110 lb (50 kg) of body weight: 10 mL will treat an 1100
(500 kg) horse.
See package insert for complete indications, precautions, warn
and use directions.
8688304
Lot No & Exp Da
LBY0280 04-2005

Carton - Top


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

Carton - Front



Carton - Left

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.

Lot No & Exp Date ▼

LBY02[illegible]0
04-200[illegible]

Marketed by
Merial Limited
Iselin, New Jersey 08830-3077

Carton - Right

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

PRECAUTIONS

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

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.

Carton - Rear

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, *Cylicostephanus* spp, *Cylicodontophorus* spp; **Pinworms** (adults and fourth-stage larvae) –*Oxyuris equi;* **Ascarids** (adults and third- and fourth-stage larvae) – *Parascaris equorum;* **Hairworm** (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.

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 110 lb (50 kg) of body weight; 10 mL will treat an 1100 lb (500 kg) horse.

See package insert for complete indications, precautions, warnings and use directions.

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%.

U.S. Pat. 4,199,569 Product **25877**

 9298600

EQVALAN® *(ivermectin)*

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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.

Marketed by
Merial Limited
Iselin, New Jersey, 08830-3077
U.S.Pat. 4,199,569

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)*

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 wide 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.

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

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.

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 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.

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.

SAFETY

EQVALAN 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.**

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

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

PRECAUTIONS

- 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.

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 waterborne 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.

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 associated 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.

HOW SUPPLIED

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.

EQVALAN® (ivermectin)

Merial Limited: Registered in England and Wales [Reg. No. 2332751] with registered offices at 22, Knightsbridge, London SW1X 7QT, England and domesticated in Delaware, USA as Merial LLC.

Marketed by
Merial Limited
Iselin, New Jersey 08830-3077

8688407

May 2000

NADA 140-439, Approved by the FDA

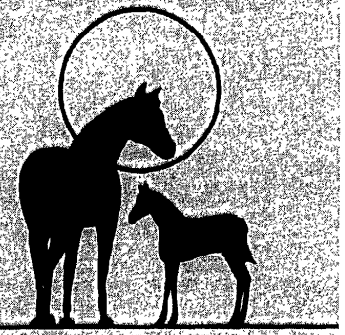
FOR VETERINARY USE ONLY

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.