

Date of Approval: AUG 9 2004

FREEDOM OF INFORMATION SUMMARY

NADA 134-314

EQVALAN Paste 1.87%

ivermectin

This supplement amends the EQVALAN (ivermectin) Paste 1.87% labeling to reflect a change in the indications section. Specifically, under the sub-heading Small Strongyles, the labeling has been revised to separate the listing of adult species from the fourth-stage larvae.

Sponsored by:

Merial Ltd.

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1. GENERAL INFORMATION:

- a. File Number: NADA 134-314
- b. Sponsor: Merial Ltd.
3239 Satellite Blvd.
Building 500
Duluth, GA 30096-4640

Drug Labeler Code: 050604
- c. Established Name: Ivermectin
- d. Proprietary Name: EQVALAN 1.87% Paste For Horses
- e. Dosage Form: Paste containing 1.87 % ivermectin
- f. How Supplied: Individual dose syringe contains sufficient paste to treat one 1250 lb horse orally. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb of body weight
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Each syringe contains 113 mg of ivermectin
- i. Route of Administration: Oral
- j. Species/Class: Equine
- k. Recommended Dosage: 91 mcg ivermectin per lb (200 mcg/kg)
- l. Pharmacological Category: Anthelmintic
- m. Indications: For treatment and control of the following parasites in horses: **Large strongyles** (adults)-*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus* and *Craterostomum acuticaudatum*; **Small Strongyles** (adults, including those resistant to some benzimidazole class compounds)-*Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*,

Cylicodontophorus spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; **Small Strongyles**-fourth stage larvae; **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)-*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.

n. Effect of Supplement:

This supplement amends the EQVALAN (ivermectin) Paste 1.87% labeling to reflect a change in the indications section. Specifically, under the sub-heading Small Strongyles, the labeling has been revised to separate the listing of adult species from the fourth-stage larvae.

2. **EFFECTIVENESS:**

This supplement revises the indications to better reflect the original effectiveness data. Specifically, the new language separates out the unspiciated fourth-stage^{*} larvae from the speciated adult small strongyles. The new language reads as follows: “**Small Strongyles** (adults, including those resistant to some benzimidazole class compounds)-*Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; **Small Strongyles**-fourth stage larvae”

No new data was required for this supplement to NADA 134-314 (original approval May 29, 1984) and this supplement did not require review of the original effectiveness data for this product.

3. TARGET ANIMAL SAFETY:

No new data was required for this supplement to NADA 134-314 (original approval May 29, 1984) and this supplement did not require review of the original target animal safety data for this product.

4. HUMAN SAFETY:

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

Human Warnings are provided on the product label as follows: "Not for use in humans. Keep this and all drugs out of the reach of children." "Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes." "Do not use in horses intended for human consumption."

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrates that EQVALAN Paste 1.87% is safe and effective for the labeled claim.

The drug is available over-the-counter for lay use. Routine deworming of horses is a widely accepted and recommended practice performed by the layperson. A diagnosis of parasite infection prior to deworming is not necessary. The syringe carton and package outsert contain detailed directions for use.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category I change. Therefore, this action did not require a reevaluation of the safety and effectiveness data in the parent application.

6. ATTACHMENTS:

Facsimile labeling is attached as indicated below:

Carton

Package Outsert

Syringe Label

1.77"

Product Z5874

For Oral Use in Horses Only

EQVALAN[®] (ivermectin) Paste 1.87%

Anthelmintic and Boticide

For Treatment of Large Strongyles, Small Strongyles, Pinworms, Roundworms (Ascarids), Hairworms, Neck Threadworms, Large-mouth Stomach Worms, Bots. See carton or attached labeling for complete indications and use directions. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

NADA 134-314, Approved by the FDA
NET WT 0.21 OZ (6.08 g)

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

Not for use in humans. Keep this and all drugs out of reach of children. Refrain from smoking or eating when handling. Wash hands after use. Avoid contact with eyes.

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Lot No &
Exp Date

Unvarnished & unprinted area
1-7/16" W x 5/16" H

Marketed by
Merial Limited
Duluth, GA 30096-4640

U.S. Pat. 4,199,569 1020-1656-00 / Rev. 06-04



(Panel to be adhered to base label)

NADA 134-314, Approved by the FDA Product 25874

EQVALAN[®] Anthelmintic and Boticide
(ivermectin) Paste 1.87%

Removes worms and bots with a single dose. Contents will treat up to 1250 lb body weight.

For Oral Use in Horses Only.

EACH SYRINGE CONTAINS 0.21 OZ (6.08 g) IVERMECTIN PASTE

Net Wt 0.21 oz (6.08 g)



Open Here

1060-1657-00



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INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. EQVALAN[®] (ivermectin) Paste provides effective treatment and control of the following parasites in horses. Large Strongyles (adults) - *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus* and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds) - *Coronocylcus* spp. including *C. coronatus*, *C. labiatus* and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocylcus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus* and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calceatus*, *C. goldi*, *C. longibursatus* and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles - Fourth-stage larvae;

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) - *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 *Dracchia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

DOSAGE AND ADMINISTRATION: This syringe contains sufficient paste to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight.

(1) While holding plunger, turn the knurled ring on the plunger 1/4 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 1/4 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 horse's mouth at the space between the teeth. (6) Depress the plunger as far as it will go, depositing paste on the back of the tongue. (7) Immediately raise the horse's head for a few seconds after dosing.

PARASITE CONTROL PROGRAM: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at

6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. EQVALAN (ivermectin) Paste effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by *Strongylus vulgaris*.

PRODUCT ADVANTAGES: Broad-spectrum Control - EQVALAN Paste kills important internal parasites, including bots and the arterial stages of *S. vulgaris*, with a single dose. EQVALAN Paste is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

ANIMAL SAFETY: EQVALAN Paste may be used in horses of all ages, including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility.

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

Not for use in humans. Keep this and all drugs out of reach of children. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse reactions in users, to obtain more information, or to obtain a MSDS, contact Merial at 1-888-637-4251.

PRECAUTIONS: EQVALAN (ivermectin) Paste 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 the syringe in an approved landfill or by incineration.

INFORMATION FOR HORSE OWNERS: Swelling and itching reactions after treatment with EQVALAN Paste have occurred in horses carrying heavy infections of neck threadworm (*Onchocerca* sp. microfilariae). These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of

summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with EQVALAN (ivermectin) Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

Merial Limited, a company limited by shares registered in England and Wales (registered number 3332751) with a registered office at PO Box 327, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 5TG, England, and domiciled in Delaware, USA as Merial LLC. U.S. Pat. 4,199,569

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