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Date of Approval: SEP 16 2005

FREEDOM OF INFORMATION SUMMARY

NADA 141-215

EQUIMAX Paste

ivermectin 1.87%/praziquantel 14.03%

This supplement provides for a revised Indications section with respect to small strongyles for EQUIMAX Paste.

Sponsored by:

Virbac AH, Inc.
3200 Meacham Blvd.
Fort Worth, TX 76137

2005-141-215

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1. GENERAL INFORMATION:

- a. File Number: NADA 141-215
- b. Sponsor: Virbac AH, Inc.
3200 Meacham Blvd.
Ft. Worth, TX 76137

Drug Labeler Code: 051311
- c. Established Name: ivermectin/praziquantel
- d. Proprietary Name: EQUIMAX
- e. Dosage Form: A paste containing ivermectin 1.87% and praziquantel 14.03%
- f. How Supplied: Individual dose syringe contains sufficient paste to treat one 1320 lb horse orally. Each weight marking on the syringe plunger delivers enough paste to treat 220 lb bodyweight
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Each milligram of EQUIMAX Paste contains 0.0187 milligram (1.87%) ivermectin and 0.1403 milligram (14.03%) praziquantel. Each syringe contains 120.1 mg of ivermectin and 897.6 mg praziquantel
- i. Route of Administration: Oral
- j. Species/Class: Equine
- k. Recommended Dosage: 91 mcg ivermectin per lb (200 mcg/kg) bodyweight and 0.68 mg praziquantel per lb (1.5 mg/kg) bodyweight
- l. Pharmacological Category: Anthelmintic and Boticide
- m. Indications: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. EQUIMAX (ivermectin/praziquantel) Paste is indicated for the treatment and control of the following parasites:
Tapeworms

Anoplocephala perfoliata

Large Strongyles (adults)

Strongylus vulgaris (also early forms in blood vessels)

Strongylus edentatus (also tissue stages)

Strongylus equinus

Triodontophorus spp.

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

Cyathostomum spp.

Cylicocyclus spp.

Cylicostephanus spp.

Cylicodontophorus spp.

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.

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 is a regulatory supplement requested by the Division of Surveillance to bring product labeling into compliance with the pioneer product. Therefore, this supplement provides for separation of small strongyle fourth-stage larvae from the small strongyle adults, which are specified in the indication section of the product labeling. In addition, it revises the Warning statement to read "Do not use in horses intended for human consumption."

2. EFFECTIVENESS:

The clinical effectiveness of the recommended dosage of 91 mcg ivermectin per pound (200 mcg/kg) of body weight and 0.68 mg praziquantel per pound (1.5 mg/kg) of body weight is contained in the original Freedom of Information Summary for NADA 141-215 dated July 11, 2003. No additional clinical effectiveness data were required for this supplement.

3. TARGET ANIMAL SAFETY:

The safety of the recommended dosage of 91 mcg ivermectin per pound (200 mcg/kg) of body weight and 0.68 mg praziquantel per pound (1.5 mg/kg) of body weight is contained in the original Freedom of Information Summary for NADA 141-215 dated July 11, 2003. The supplemental approval dated July 30, 2004 provided for the safe use of EQUIMAX Paste in breeding, pregnant or lactating mares.

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 supplement.

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 eating and smoking 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 Pfizer at 1-800-366-5288." The Virbac product is distributed by Pfizer Inc.

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 demonstrate that EQUIMAX Paste when used under the labeled conditions of use is safe and effective for the treatment and control of roundworms (ascarids, strongyles and lungworms), tapeworms and bots in horses.

The drug is available over-the-counter for lay use because adequate directions for use are provided and oral antiparasitic treatments in horses are routinely performed by the layperson.

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 II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

EQUIMAX Paste is under the following U.S. patent number:

<u>U.S. Patent Number</u>	<u>Date of Expiration</u>
5,824,653	11/27/2015

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

Package Insert
Syringe Label
Carton Label

EQUIMAX™

(ivermectin 1.87%/praziquantel 14.03%)



Paste

Anthelmintic and Boticide

FOR ORAL USE IN HORSES ONLY

Removes worms and bots with a single dose.

Contents will treat up to 1320 lb body weight.

Net Weight: 0.225 oz (6.42 g)

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Equimax (ivermectin/praziquantel) Paste is indicated for the treatment and control of the following parasites:

Tapeworms

Anoplocephala perfoliata

Large Strongyles (adults)

Strongylus vulgaris (also early forms in blood vessels)

S. edentatus (also tissue stages)

S. equinus

Triodontophorus spp.

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

Cyathostomum spp.

Cylicocyclus spp.

Cylicostephanus spp.

Cylicodontophorus spp.

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.

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: This syringe contains sufficient paste to treat one 1320-lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) and 0.68 mg praziquantel per lb (1.5 mg/kg) of body weight. Each weight marking on the syringe plunger delivers enough paste to treat 220 lb (100 kg) of 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.

75-0239-03

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 4 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. Equimax Paste effectively controls gastrointestinal nematodes, cestodes and bots of horses. Regular treatment will reduce the chances of colic caused by *Anoplocephala perfoliata* and verminous arteritis caused by *Strongylus vulgaris*.

Product Advantages: Broad-spectrum Control: Equimax Paste kills important internal parasites, including tapeworms, bots and the arterial stages of *S. vulgaris*, with a single dose. Equimax Paste contains two potent antiparasitic agents that are neither benzimidazoles nor organophosphates.

SAFETY: EQUIMAX Paste may be used in horses 4 weeks of age and older. Stallions and breeding, pregnant or lactating mares may be treated without adverse effects on fertility.

In a tolerance study in which 3- to 4-week-old foals were treated at 10X once, loose watery stools were observed on post-treatment days 1, 2, and 5-9 in one foal. These signs resolved without treatment by day 10, and no other foals were affected.

In a reproductive safety study, eleven mares were treated with a 3X dose of EQUIMAX Paste every two weeks throughout breeding, pregnancy and lactation, up until the foal was three months of age. Ten mares served as controls and were treated with the vehicle paste in a similar manner. An increased incidence of colic was observed in treated mares as compared to control mares. In addition, elevations of GGT and AST were more frequent in the 3X treated mares, and in two mares these enzymes were elevated at the time of colic episodes. One treated mare was dropped from the study because she did not conceive after three breeding attempts. Two treated mares had abnormally short diestrous periods of two days and eight days on the first estrous cycle following the birth of the study foal. In addition, one of these two mares failed to ovulate in the second and third estrous cycles.

In the first few weeks of life, foals born to the 3X treated mares had a higher incidence of transient ocular discharge and gastrointestinal disturbances (loose stools, diarrhea) and depression requiring medical intervention as compared to foals born to control mares.

PRECAUTIONS: Equimax Paste has been formulated specifically for use in horses and ponies only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

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

HUMAN WARNINGS: Not for use in humans. Keep this and all drugs out of the reach of children. Refrain from eating or smoking 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 Pfizer at 1-800-366-5288.

ENVIRONMENTAL WARNINGS: 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.

Store at room temperature (25°C/77°F), with excursions permitted between 15°–30°C (59°–86°F).

NOTE TO USER: Swelling and itching reactions after treatment with ivermectin 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 Equimax Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

To report adverse reactions, call Pfizer Animal Health at 1-800-366-5288.

NADA #141-215, Approved by FDA

Manufactured by:

Virbac AH Inc.

3200 Meacham Blvd

Fort Worth, Texas 76137

U.S. Patent No. 5,824,653

Distributed by:

Pfizer Animal Health

Exton, PA 19341, USA

Div. of Pfizer Inc

NY, NY 10017

Made in USA

Equimax is a trademark of Virbac SA.

EQUIMAX™

(ivermectin 1.87%/
praziquantel 14.03%)

NADA #141-215, Approved by FDA

Paste
Anthelmintic and Boticide
FOR ORAL USE IN HORSES ONLY

Net Weight: 0.225 oz
(6.42 g)

Pfizer

EQUIMAX™

(ivermectin 1.87%/praziquantel 14.03%)

Pfizer

EQUIMAX™

(ivermectin 1.87%/praziquantel 14.03%)

For the treatment and control of roundworms (ascarids, strongyles and lungworms), tapeworms, and bots in horses with a single dose.

Contents will treat up to 1320 lb body weight.

FOR ORAL USE IN HORSES ONLY

Net Weight: 0.225 oz (6.42 g)

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Anthelmintic and Boticide

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