

Date of Approval: DEC 18 2008

# FREEDOM OF INFORMATION SUMMARY

Supplemental Abbreviated New Animal Drug Application

ANADA 200-286

PHOENECTIN Paste 1.87%  
(ivermectin)  
Oral Paste  
Horses

Effect of Supplement: This supplement requests the addition of the following parasite species that are no longer protected by marketing exclusivity: *Craterostomum acuticaudatum*, *Coronocylus coronatus*, *Coronocylus labratus* and *Petrovinema poculatum*

Sponsored by:

IVX Animal Health, Inc.

FDA-2008-N-0039

FOIS

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

- a. File Number: ANADA 200-286
- b. Sponsor: IVX Animal Health, Inc.  
3915 South 48<sup>th</sup> Street Ter.  
St. Joseph, MO 64503  
  
Drug Labeler Code: 059130
- c. Established Name: Ivermectin
- d. Proprietary Name: PHOENECTIN Paste 1.87%
- e. Dosage Form: Oral Paste
- f. How Supplied: 6.08 g and 7.30 g sizes in IVX-style and Sure-Grip style syringes
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 1.87% ivermectin
- i. Route of Administration: Oral
- j. Species/Class: Horses, not for meat production
- k. Recommended Dosage: Each syringe contains sufficient paste to treat five 1,250 lb horses or a total of 6,250 lb body weight at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) of body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight.
- l. Pharmacological Category: Antihelmintic and boticide
- m. Indications: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. PHOENECTIN (ivermectin) Paste 1.87% 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) – *Coronocylus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocylus* 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. Pioneer Product:

EQVALAN Paste 1.87%; ivermectin; NADA 134-314; Merial Ltd.

o. Effect of Supplement:

This supplement requests the addition of labeling claims that are no longer protected by marketing exclusivity for the following parasite species: *Craterostomum acuticaudatum*, *Coronocylus coronatus*, *Coronocylus labratus* and *Petrovinema poculatum*.

**2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:**

Refer to the original Freedom of Information (FOI) Summary (ANADA 200-286, E-0002) dated September 20, 2000, for more detail.

**3. 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 ANADA.

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."

**4. AGENCY CONCLUSIONS:**

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that PHOENECTIN Paste 1.87%, when used under the proposed conditions of use, is safe and effective for its labeled indications.

**5. ATTACHMENTS:**

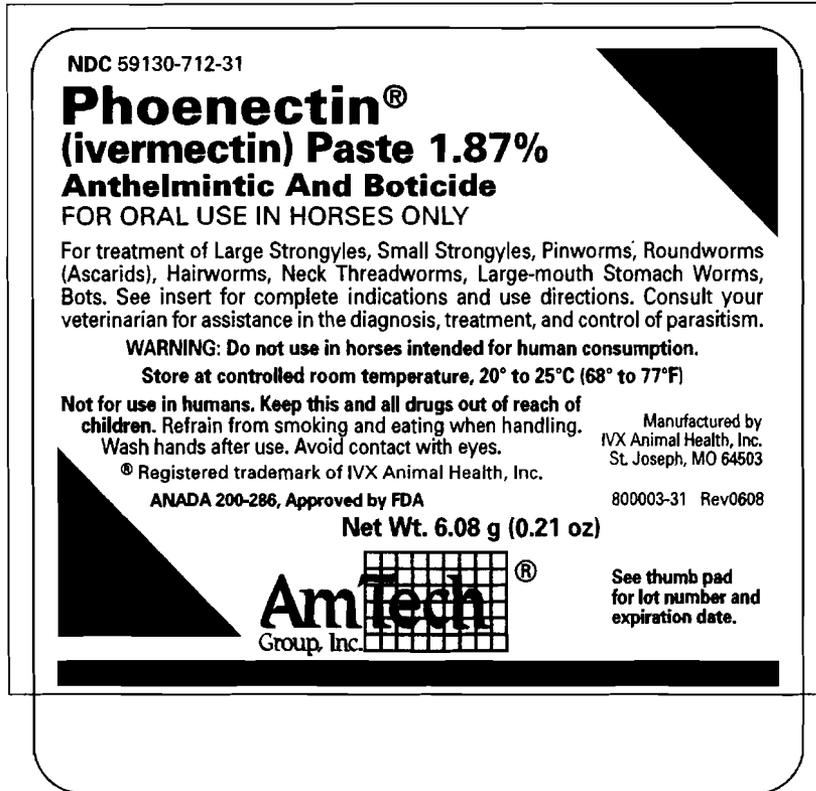
Facsimile Generic Labeling and Currently Approved Pioneer Labeling are attached as indicated below:

Generic Labeling:

Syringe label; package insert; carton label; display tray

Pioneer Labeling:

Syringe label; package insert; carton label



200%

**CUSTOMER PROOF • pdf format • CHECK CAREFULLY!**  
 Tabco, Inc. • (913) 287-3333 • fax (913) 287-3338 • 1323 S. 59th street • Kansas City, KS 66106 • www.tabcoinc.com

Customer: IVX Animal Health, Inc. P.O. #: Christina CYREL #: 25450-T (In)  
 Customer Service: Kathy Roper • kroper@tabcoinc.com

Date 08/29/07 09/27/07 06/25/08 07/03/08

Unwind #: 1

desc.: <u>Phoenectin</u>	size: <u>2.0</u> " x <u>2.0</u> "
varnish: <input checked="" type="checkbox"/> lamination: <input type="checkbox"/>	colors: <u>black</u> <u>1797 red</u> <u>water varn.</u>
<input checked="" type="checkbox"/> pattern	
<input type="checkbox"/> flood	

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Approved by: \_\_\_\_\_  OK as shown  make corrections and resubmit  
 OK w/ corrections  Date: \_\_\_\_\_

NDC 59130-712-31

**Phoeneectin®**  
(ivermectin)  
Paste 1.87%

**Anthelmintic and Boticide**

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

**For Oral Use in Horses Only**

ANADA 200-286, Approved by FDA  
Net Wt. 6.08 g (0.21 oz)



the plunger as far as it will go, depositing paste on the back of the tongue. (5) 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. Phoeneectin® (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** - Phoeneectin® (ivermectin) Paste kills important internal parasites, including bots and the arterial stages of *S. vulgaris*, with a single dose. Phoeneectin® (ivermectin) Paste is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

**ANIMAL SAFETY** - Phoeneectin® (ivermectin) 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 reaction in users, to obtain more information, or to obtain a MSDS, contact IVX Animal Health at 1-800-759-3664.

**PRECAUTIONS:** Phoeneectin® (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.

**INDICATIONS:** Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Phoeneectin® (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. lebratus*, *Cyathostomum* spp. including *C. cetinum* and *C. pateratum*, *Cylicocylcus* 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 *Petrovinae pauculatum*; **Small Strongyles** - Fourth-stage larvae; **Piseworms** (adults and fourth-stage larvae) - *Oxyuris equi*; **Ascarids** (adults and third- and fourth-stage larvae) - *Parascaris equorum*; **Hairworms** (adults) -

**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 Phoeneectin® (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 Phoeneectin® Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

**EACH SYRINGE CONTAINS 6.08 g (0.21 oz) IVERMECTIN PASTE**

*Trichostrongylus axei*; **Large-mouth Stomach Worms** (adults) - *Habronema muscae*; **Bots** (oral and gastric stages) - *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; **Longworms** (adults and fourth-stage larvae) - *Dicrocoelium arnfieldi*; **Intestinal Threadworms** (adults) - *Strongyloides wostri*; **Summer Sores** caused by *Habronema* and *Draeschia* 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 to the right so the side nearest the barrel is at the prescribed weight marking. (2) Make sure that the horse's mouth contains no feed. (3) Remove the cover from the tip of the syringe. (4) Insert the syringe tip into the horse's mouth at the space between the teeth. (5) Depress

Store at controlled room temperature, 20° to 25°C (68° to 77°F).

800003-31 Rev0608

Made in U.S.A.

\*Registered trademark of IVX Animal Health, Inc.

Manufactured by IVX Animal Health, Inc. St. Joseph, MO 64503

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Tabco, Inc. • (913) 287-3333 • fax (913) 287-3338 • 1323 S. 59th street • Kansas City, KS 66106 • www.tabcoinc.com

Customer: IVX Animal Health, Inc. P.O. #: ---- CYREL #: 27409-T (In)

Customer Service: Kathy Roper • kroper@tabcoinc.com

Date 08/30/07 09/07/07 09/27/07 07/08/08

Unwind #: \_\_\_\_\_

desc.: <u>Phoeneectin</u>	size: <u>4.50</u> " x <u>3.25</u> "
varnish: <input type="checkbox"/> pattern	colors: <u>black</u> <u>1797 red</u>
<input type="checkbox"/> flood	
lamination: <input type="checkbox"/>	

**SHEETS**

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Approved by: \_\_\_\_\_

OK as shown       make corrections and resubmit

OK w / corrections      **Date:** \_\_\_\_\_

Job#: B330  
File: Phoenectin 7.3 IFC  
Colors: PMS 1797, Black  
Date: 07/18/08

**INDICATIONS:** Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Phoenectin® (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) - *Coronocylus* spp. including *C. coronatus*, *C. labiatus* and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocylus* 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 pocolatum*; **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 microfilariæ, *Onchocerca* sp.

**DOSAGE AND ADMINISTRATION:** This syringe contains sufficient paste to treat one 1500 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 to the right so the side nearest the barrel is at the prescribed weight marking. (2) Make sure that the horse's mouth contains no feed. (3) Remove the cover from the tip of the syringe. (4) Insert the syringe tip into the horse's mouth at the space between the teeth. (5) Depress the plunger as far as it will go, depositing paste on the back of the tongue. (6) 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. Phoenectin® (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** - Phoenectin® (ivermectin) Paste kills important internal parasites, including bots and the arterial stages of *S. vulgaris*, with a single dose. Phoenectin® (ivermectin) Paste is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

**ANIMAL SAFETY:** Phoenectin® (ivermectin) 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.

Manufactured by  
IVX Animal Health, Inc.  
St. Joseph, MO 64503

Iss0608

800003-38



Lot No.  
Exp. Date

**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 IVX Animal Health at 1-800-759-3664.

**PRECAUTIONS:** Phoenectin® (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 Phoenectin® (ivermectin) Paste have occurred in horses carrying heavy infections of neck threadworm (*Onchocerca* sp.) microfilariæ. These reactions were most likely the result of microfilariæ 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 Phoenectin® (ivermectin) Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

NDC 59130-712-38

Removes worms and bots with a single dose

**Phoenectin® Paste 1.87%** ANTHELMINTIC AND BOTICIDE  
(ivermectin)

FOR ORAL USE IN HORSES ONLY

Contents will treat up to 1500 lb body weight • Net Wt. 7.30 g (0.25 oz)

ANADA 200-286, Approved by FDA



**Phoenectin® (ivermectin) Paste 1.87%** ANTHELMINTIC AND BOTICIDE

Store at controlled room temperature, 20° to 25°C (68° to 77°F).

Phoenectin® and AmTech® are registered trademarks of IVX Animal Health, Inc.

Phoenectin®  
(ivermectin)  
Paste 1.87%

MDC 59130-712-31



ANADA 200-286, Approved by FDA  
Net Wt: 12 x 6.08 g (0.21 oz)

Front panel

# Phoenectin<sup>®</sup> (ivermectin) Paste 1.87%

ANTHELMINTIC AND BOTICIDE

FOR ORAL USE IN HORSES ONLY

Net Wt: 12 x 6.08 g (0.21 oz)

Manufactured by  
IVX Animal Health, Inc.  
St. Joseph, MO 64503

Lot No.

Exp. Date



800003-31  
REV0807

Right side panel

Product 25874

For Oral Use in Horses Only

**EQVALAN**<sup>®</sup>  
(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 (6.00 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.

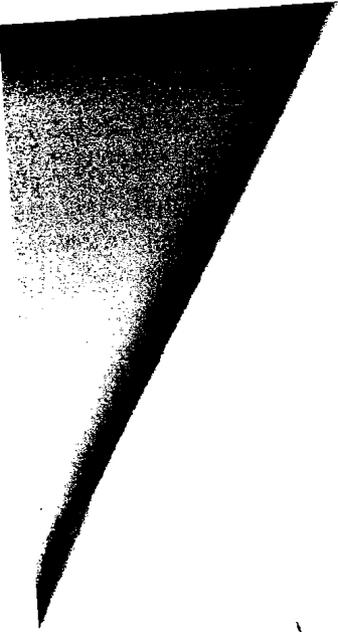
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Lot No &  
Exp Date ▶

Marketed by  
Merial Limited  
Duluth, GA 30096-4640

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





EQVALAN<sup>™</sup> (ivermectin) Anthelmintic and Boticide  
 Net Wt 0.21 oz (6.08 g)



1060-1657-00

1060-1657-00  
 EQVALAN (ivermectin) Anthelmintic and Boticide  
 Net Wt 0.21 oz (6.08 g)

**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. colinatum* and *C. pateratum*, *Cylicocylcus* spp. including *C. insigne*, *C. leptostomum*, *C. nasatus* and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus* and *C. minutus*, and *Petrovinnema 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*; **Boets** (oral and gastric stages) - *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; **Lungworms** (adults and fourth-stage larvae) - *Dicycoelus arnfieldi*; **Intestinal Threadworms** (adults) - *Strongyloides westeri*; **Summer Sores** caused by *Habronema* and *Drosophila* 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

3

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.

4

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

5

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 domesticated in Delaware, USA as Merial LLC. U.S. Pat. 4,199,569

EQVALAN is a registered trademark of Merial Limited. Copyright © 2004 Merial Limited. All Rights Reserved. Marketed by Merial Limited, 3239 Satellite Blvd, Duluth, GA 30096-4640 Rev. 06-04

6

Removes worms and bots with a single dose  
Contents will treat up to 1250 lb body weight  
For Oral Use in Horses Only  
NADA 134-514, Approved by the FDA

# EQVALAN

(ivermectin) Paste 1.87%



**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.

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