

Date of Approval: JAN 19 2005

FREEDOM OF INFORMATION SUMMARY

Original Abbreviated New Animal Drug Application

ANADA 200-326

BIMECTIN Paste 1.87%
(ivermectin)

Oral Anthelmintic Paste for use in Horses

For the treatment and control of specific internal parasites in horses

Sponsor:

Cross Vetpharm Group Ltd.

2005-200-326

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FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-326
- b. Sponsor: Cross Vetpharm Group Ltd.
Broomhill Road
Tallaght, Dublin 24
Ireland
- Drug Labeler Code: 061623
- c. Established Name: Ivermectin
- d. Proprietary Name: BIMECTIN Paste 1.87%
- e. Dosage Form: Paste
- f. How Supplied: Individual syringe containing 6.08 g paste
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 1.87% ivermectin
- i. Route of Administration: Oral
- j. Species/Class: Horses, not intended for human consumption
- k. Recommended Dosage: 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 $\frac{1}{4}$ 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 $\frac{1}{4}$ turn to the right. (3) Make sure 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.
- l. Pharmacological Category: Anthelmintic

m. Indications:

BIMECTIN 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*; **Small Strongyles** (adults, including those resistant to some benzimidazole class compounds) – *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*; *Cylicocycclus* 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*; **Small Strongyles** – Fourth-stage larvae; **Pinworms** (adults and fourth-stage larvae) – *Oxyuris equi*; **Ascarids** (adults, third-stage 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-stages 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.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Blood-level *in vivo* Bioequivalence Study:

Title: A Two-Way Single-Dose Bioequivalence Study with Ivermectin Oral Paste in Healthy Horses

Study Objective: To demonstrate that Cross Vetpharm Group Ltd's oral ivermectin paste is bioequivalent to Merial Ltd's EQVALAN Paste (NADA 134-314)

Principle Investigator: Dr. John Brennan

Study Location: Shur-Gain Agresearch, Inc.
 Burford, Ontario
 CANADA

This study was a randomized, single dose two-period crossover design. The pioneer product is Merial Ltd.'s EQVALAN (ivermectin) Paste approved under NADA 134-314 and the generic product is Cross Vetpharm Group Ltd's oral ivermectin paste. The study used 24 horses, 12 males and 12 females. The horses were randomly assigned to two groups containing 12 animals each. In Period 1, animals assigned to Group 1 received the reference product and animals assigned to Group 2 received the generic product. In Period 2, the animals in each Group received the opposite drug provided in Period 1. In each Period, blood samples were taken pre-dose and post-dose at 1, 3, 4, 5, 6, 7, 9, 12, 15, 18, 24, 36, 48, 72, 168, 336, and 504 hours. A washout time of 42 days was used.

Serum samples were submitted for ivermectin b1a analysis on an HPLC system at the completion of the study. The results were calculated using a linear regression analysis. Pen or gender or their interactions were not involved in the data analysis.

The table below summarizes the results of the *in vivo* bioequivalence study. Both pivotal parameters for determining bioequivalence, Area Under the Curve (AUC) and Maximum Concentration (C_{max}), are within the 80% to 125% bounds for logarithmically transformed data. Since the significance of Time to Maximum Concentration (T_{max}) is a veterinary medical decision, this parameter is represented in mean values only.

Variable	Bimeda Mean	Merial Mean	Lower	Upper
Time to Max. Concentration (hours)	4.39	4.70	NA	NA
Area under Curve $\log_e AUC_{0-\log}$	8.2193	8.1273	100.0%	120.2%
Maximum Concentration $\log_e C_{MAX}$	4.2105	4.0948	101.1%	124.6%

Both variables, the logarithmic area under the curve and logarithmic maximum concentration, satisfied the bioequivalence criteria. These data confirm equivalent drug bioavailability between the generic and pioneer products.

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: "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. 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 BIMECTIN Paste 1.87% for use in horses, when used under the proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and current approved pioneer labeling are attached as indicated below:

Generic Labeling: BIMECTIN Paste, ANADA 200-326
Syringe label; carton label; package insert

Pioneer Labeling: EQVALAN Paste, NADA 134-314
Syringe label; carton label; package insert

PS Label

VARNISH LINE

Bimectin™

(ivermectin) Paste 1.87%

Anthelmintic and Boticide

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

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.

ANADA# 200-326, Approved by FDA
For Oral Use in Horses Only

Net Weight: 0.21 oz (6.08 g)

Manufactured by: Bimeda-MTC Animal Health Inc.
Cambridge, Ontario, Canada N3C 2W4

Manufactured for: Bimeda, Inc. Riverside, MO 64150

Bimeda, Inc. and Bimeda-MTC Animal Health Inc.
are Divisions of Cross Vetpharm Group Ltd.

Bimectin is a Trademark of Bimeda, Inc.



Product No. 18IM004
8BIM011

September, 2004

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SEPTEMBER 17 2004

150% for text

VARNISH LINE

Bimectin™

(ivermectin) Paste 1.87%

Anthelmintic and Boticide

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

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For Oral Use in Horses Only

Net Weight: 0.21 oz (6.08 g)

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are Divisions of Cross Vetpharm Group Ltd.

Bimectin is a Trademark of Bimeda, Inc.



Product No. 18IM004
8BIM011

September, 2004

Individual Carton

WARNING: Do not use in animals indicated for human consumption. Keep this and all other medications away from children. Keep this and all other medications away from children. Keep this and all other medications away from children. Keep this and all other medications away from children.

PRECAUTIONS: Bimectin[™] (ivermectin) Paste has been found to be safe in horses. However, it is not known if it is safe in other species. Do not use in animals for which it is not labeled. Do not use in animals for which it is not labeled. Do not use in animals for which it is not labeled.

INFORMATION FOR HORSE OWNERS: Showing and riding horses after treatment with Bimectin[™] (ivermectin) Paste has been found to be safe. However, it is not known if it is safe in other species. Do not use in animals for which it is not labeled. Do not use in animals for which it is not labeled. Do not use in animals for which it is not labeled.

Bimectin[™]
(ivermectin) Paste 1.87%

Bimectin[™]
(ivermectin) Paste 1.87%
Anthelmintic and Boticide

Net Wt. 0.21 oz (6.08 g)
Removes worms and bots with a single dose.
Contents will treat up to 1250 lb body weight
For Oral Use in Horses Only
ANADA-200-376. Approved by FDA

Bimectin[™]
(ivermectin)



Apple Flavored!

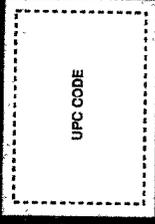
Bimectin[™]
(ivermectin) Paste 1.87%



INDICATIONS: Bimectin[™] (ivermectin) Paste is indicated for the treatment of horses for the following internal parasites: Pinworms, Small Strongyles, Large Strongyles, and bots. Bimectin[™] (ivermectin) Paste is also indicated for the treatment of horses for the following external parasites: Fleas, Lice, and ticks. Bimectin[™] (ivermectin) Paste is also indicated for the treatment of horses for the following conditions: Anthelmintic resistance, Bot infestation, and respiratory tract infections.

PRECAUTIONS: Bimectin[™] (ivermectin) Paste has been found to be safe in horses. However, it is not known if it is safe in other species. Do not use in animals for which it is not labeled. Do not use in animals for which it is not labeled. Do not use in animals for which it is not labeled.

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SEPTEMBER 17 2004

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Bimectin™

(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# 200-326, Approved by FDA

Net Wt. 0.21 oz (6.08 g)

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. **Bimectin™** (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*; **Small Strongyles** (adults, including those resistant to some benzimidazole class compounds)- *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*; **Small Strongyles** - Fourth stage larvae; **Pinworms** (adults and fourth-stage larvae)-*Oxyuris equi*; **Ascarids** (adults, third-stage 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 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.

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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.

EQVALAN is a registered trademark of Merial Limited. Copyright © 2004 Merial Limited. All Rights Reserved.

Lot No & Exp Date

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

Marketed by
Merial Limited
Duluth, GA 30096-4640

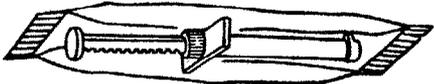
U.S. Pat. 4,199,369 1020-1656-00 / Rev. 06-04



EQUALAN®
(ivermectin) Paste 1.87%

Product 25874
U.S. Pat. 4,199,566
EQVALAN® is a registered trademark of Merial Limited.
Copyright © 2004 Merial Limited.
All Rights Reserved.

SEALED FOR SECURITY. IF BROKEN, DO NOT ACCEPT.



EQUALAN®
(ivermectin) Paste 1.87%

Andrew White and Bobbie
White, VMD, MS, PhD
MSD Animal Health

NADA 134-314, Approved by the FDA

Removes worms and bots with a single dose.
Contents will treat up to 1250 lb body weight
For Oral Use in Horses Only

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

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)** - *Coronocytus* spp. including *C. coronatus*, *C. labiatus* and *C. labratus*, *Cyathostomum* spp. including *C. caninum* 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)** - *Dictyoaculus 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 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 (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.

1030-1658-00

Rev. 06-04



Lot No & Exp Date ▼

Unvarnished area
1-1/2" W x 1" H

Marketed by Merial Limited
3239 Satellite Blvd., Duluth, GA 30096-4640

Merial Limited, a company limited by shares registered in England and Wales (registered number 3322791) with a registered office at PO Box 377, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 5TG, England, and domiciled in Delaware, USA as Merial LLC.

SEPTEMBER 17 2004

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

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ANIMAL SAFETY: **Bimectin™** (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 reactions in users, to obtain more information or to obtain a MSDS, contact Bimeda, Inc. at 1-888-524-6332.

PRECAUTIONS: **Bimectin™** (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 **Bimectin™** (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 **Bimectin™** (ivermectin) Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

Bimectin is a Trademark of Bimeda, Inc.
Bimeda, Inc. and Bimeda-MTC Animal Health Inc
are Divisions of Cross Vetpharm Group Ltd.

Product No. 1BIM004
8BIMXXX

September, 2004



Manufactured for
Bimeda, Inc
Riverside, MO 64150

Manufactured by
Bimeda-MTC Animal Health Inc.
Cambridge, Ontario, Canada N3C 2W4

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NADA 134-314, Approved by the FDA

Product 25874

EQVALAN[®]
(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.

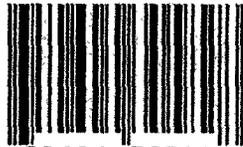
EACH SYRINGE CONTAINS 0.21 OZ (6.08 g) IVERMECTIN PASTE

Net Wt 0.21 oz (6.08 g)



Open Here

1060-1637-00



3 50604-30582 8

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. cotinatum* and *C. pateratum*, *Cycticyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus* and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calcatus*, *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*; Bots (oral and gastric stages) - *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae) - *Dictyocaulus viviparus*; 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.

DOSE 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.

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