

HFA 305

FREEDOM OF INFORMATION SUMMARY

Abbreviated New Animal Drug Application

ANADA 200-320

EQUELL (ivermectin) Paste

Sponsor:

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

ANADA 200-320

FOIS-1

1. GENERAL INFORMATION:

FILE NUMBER: 200-320

SPONSOR: Virbac AH, Inc.
Fort Worth, TX 76137

Drug Labeler Code 051311

ESTABLISHED NAME: Ivermectin Paste

PROPRIETARY NAME: EQUELL™ (ivermectin) Paste

DOSAGE FORM: Oral Paste

HOW SUPPLIED: Dose syringe containing 6.42 grams of product.

HOE DISPENSED: OTC

AMOUNT OF ACTIVE INGREDIENTS: Each milligram of the paste contains 0.0187 milligram (1.87 %) ivermectin.

ROUTE OF ADMINISTRATION: Oral

SPECIES: Equine

RECOMMENDED DOSAGE: The dose rate is 91 mcg ivermectin per pound (200 mcg/kg) of body weight.

PHARMACOLOGICAL CATEGORY: Antiparasitic

PIONEER PRODUCT: Eqvalan® (ivermectin) Paste, Merial Ltd., NADA 134-314.

INDICATIONS FOR USE:

Equell is indicated for the effective treatment and control of the following parasites or parasitic conditions in horses:

Large strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels),

S. edentatus (also tissue stages), *S. equinus*, *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*.

Hairworms (adults): *Trichostrongylus axei*.

Largemouth stomach worms (adults): *Habronema muscae*.

Neck threadworms (microfilariae): *Onchocerca* spp.

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.

2. ANIMAL SAFETY AND EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988; First GADPTRA Policy Letter), 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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are required for approval of an ANADA. An ANADA approval is based on a demonstration that the generic product is bioequivalent to the pioneer product.

The following studies were completed to provide evidence of blood-level bioequivalence of the generic and pioneer ivermectin pastes in horses:

Bioequivalence study 595.04/60001 (GLP)

A BIOEQUIVALENCE STUDY OF VIRBAC'S IVERMECTIN ORAL PASTE AND EQVALAN[®] IN HORSES

Study Director/Location: Craig Reinemeyer, D.V.M., Ph.D.
East Tennessee Clinical Research, Inc.
Knoxville, TN

Summary: After meeting entrance criteria, 28 adult horses (14 castrated males; 14

females) were ranked by weight within each sex. Within each sex, replicates of two horses were randomly assigned to one of two treatment sequences, generic test article followed by pioneer control article or pioneer control article followed by generic test article. Animals were given the first drug of the assigned sequence during the first treatment period and the second drug of the assigned sequence during the second treatment period. Treatments consisted of a single oral administration of 200 mcg of generic or pioneer ivermectin per kg of body weight. For the second treatment of the sequence, horses received a single oral administration of 200 mcg of generic or pioneer ivermectin per kg of body weight as per treatment assignment. There was a 35-day washout interval between the two periods of the crossover design.

Blood samples for each animal, for each period of the study were taken at the following times, 0 hour and (hours after drug administration), 0.5, 1, 2, 4, 6, 8, 12, 24, 36, 48, 72, 96, 120, 144, 168, 240, 336, and 504. Ivermectin concentrations in plasma were quantified using a validated HPLC method with fluorescence detection (excitation, 360 nm, and emission, 470 nm, wavelengths). The assayed ivermectin plasma levels in the blood of the test animals from the 0 hour sample through the hour 504 sample were statistically analyzed with an analysis of variance procedure, following the 2000 Bioequivalence Guideline.

The area under the plasma concentration curves (AUC estimated from time 0 to last quantifiable concentration) were computed using the trapezoidal method. The maximum concentration measured for all time periods (C_{max}) was determined. Statistical evaluation of AUC and C_{max} values were based upon the Ln-transformed estimates. The corresponding confidence intervals about the ratio of treatment means were conducted in accordance with the algorithms described in the 2000 Bioequivalence Guidance document

Results and Conclusions:

The results of the *in vivo* bioequivalence study are provided in Table 1.

Table 1: Results of the *in vivo* bioequivalence study

Variable	Virbac [arithmetic mean (%CV)]	Merial [arithmetic mean (%CV)]	Lower Conf. Lim.	Upper Conf. Lim.
AUC ($\mu\text{g}\cdot\text{hr}/\text{mL}$)	2371 (54)	2614 (55)	-18.4%	+3.8%
C_{max} ($\mu\text{g}/\text{mL}$)	37.5 (46)	42.0 (53)	-21.2%	+10.2%

The exponentiated value of the lower confidence limit about the ratio of the test/reference AUC values was ≥ 0.8 and the corresponding value for the upper limit was ≤ 1.25 . The exponentiated value of the lower confidence limit about the ratio of the test/reference

C_{max} values was ≥ 0.7878 and the corresponding value for the upper limit was ≤ 1.25 . The corresponding T_{max} values were 4.6 hr and 3.2 hrs for the test and reference products respectively.

Due to the very large within-subject variability observed with these products (residual errors from the ANOVA, expressed as %CV for AUC and C_{max} , were 26.9% and 38% respectively), the 11% difference in C_{max} prevented the confidence limits from being contained within the strict 0.80 – 1.25 boundary defining product bioequivalence. Importantly, it was noted that the intersubject variability was similar across treatment groups (refer to Table 1). In a similarly conducted study on 28 horses for the European regulatory authorities (see below), the test and reference products (which were manufactured in a manner identical to that used for the US formulations) succeeded in meeting US-type bioequivalence criteria (0.80 – 1.25). Therefore, given the high variability associated with the test and reference products, the 1% deviation from traditional US bioequivalence criteria for C_{max} , and the success of the European bioequivalence investigation, the US FDA concludes that Equell and Eqvalan are bioequivalent. “

Adverse events observed during the study included transient tremors, pawing and agitation in one horse and fasciculation of muscles in all limbs in another. Both horses had received the generic product and in both cases the clinical signs resolved spontaneously without medical intervention.

Supportive Bioequivalence Study 595.04/4001

DETERMINATION OF THE BIOEQUIVALENCE OF TWO IVERMECTIN FORMULATIONS IN HORSES.

Investigator/Study Location: Bruce Chick B.V.Sc., Dip. Ag. Econs.,
Dip. Diag. Path
Veterinary Health Research PTY Ltd.
Colin Blumer Animal Health Laboratory
West Armidale, NSW. Australia

Summary: After meeting entrance criteria, 28 adult horses (14 castrated males; 14 females) were ranked by weight within each sex. Within each sex, replicates of two horses were randomly assigned to one of two treatment sequences, generic test article followed by pioneer control article or pioneer control article followed by generic test article. Animals were given the first drug of the assigned sequence during the first treatment period and the second drug of the assigned sequence during the second

treatment period. Treatments consisted of a single oral administration of 200 mcg of generic or pioneer ivermectin per kg of body weight. For the second treatment of the sequence, horses received a single oral administration of 200 mcg of generic or pioneer ivermectin per kg of body weight. There was a 35-day washout interval between the two periods of the crossover design.

Blood samples for each animal, for each period of the study were taken at the following times, 0 hour and (hours after drug administration), 0.5, 1, 2, 4, 6, 8, 12, 24, 36, 48, 72, 96, 120, 144, 168, 240, 336, and 504. Ivermectin concentrations in plasma were quantified using a validated HPLC method with fluorescence detection (excitation, 360 nm, and emission, 470 nm, wavelengths). The assayed ivermectin plasma levels in the blood of the test animals from the 0 hour sample through the hour 504 sample were statistically analyzed with an analysis of variance procedure, following the 2000 Bioequivalence Guideline.

The area under the plasma concentration curves (AUC estimated from time 0 to last quantifiable concentration) were computed using the trapezoidal method. The maximum concentration measured for all time periods (C_{max}) was determined. Statistical evaluation of AUC and C_{max} values were based upon the Ln-transformed estimates and the corresponding confidence intervals about the ratio of treatment means were conducted in accordance with the algorithms described in the 2000 Bioequivalence Guidance document

Results and Conclusions: The exponentiated value of the lower confidence limit about the ratio of test/reference AUC values was ≥ 0.8 and the corresponding values for the upper limit was ≤ 1.25 . The exponentiated value of the lower confidence limit about the ratio of test/reference C_{max} values was ≥ 0.80 and the corresponding values for the upper limit was ≤ 1.25 . Therefore, the study objective to determine the bioequivalence of generic and pioneer ivermectin 1.87% paste by serum bioavailability was achieved. T_{max} did not satisfy the criteria in the *Bioequivalence Guidance*, but there is no reason to expect the difference in T_{max} will affect the efficacy of the drug, since both AUC and C_{max} are bioequivalent and the product is administered as a single dose.

3. HUMAN SAFETY:

Human Safety Relative to Food Consumption:

None required as Ivermectin Paste 1.87% is intended for use only in horses. The labeling includes the statement:

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

Human Safety Relative to Possession, Handling, and Administration:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This is an Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Ivermectin Paste 1.87% were established by demonstration of bioequivalence to the pioneer product, Eqvalan[®] Paste for Horses (NADA 134-314, Merial Ltd.).

This generic product and the pioneer product have identical labeling indications for the use in horses. The route and method of administration of the two drugs are identical. Both drugs are administered orally. The generic and pioneer products contain the same active ingredients.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Ivermectin Paste 1.87 % is safe and effective for its labeled indications when used under the proposed conditions of use.

5. LABELING (Attached)

1. Generic labeling:

Package Insert
Container Label
Carton Label

2. Pioneer Labeling

Package Insert
Container Label
Carton Label

Equell™
(ivermectin)



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)

Paste 1.87%
Anthelmintic and Boticide

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Equell (ivermectin) Paste provides effective 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.

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)

Dictyoaulus 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) of body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb (114 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.

75-0238-00



Pfizer	Project Name	
	Equell	
PACKAGE DESIGN & DEVELOPMENT Animal Health	Project Number	
	1915	
Editor	Michele Brettmann	
Project Team Leader	Paige Holpar	
Artist	Ron VanValkenburg	
Proofreader	Diane Mattison	
Part Number	Draft	Date
75-0238-00	3	16MAY02
Dimensions: 8 1/4" (H) X 5 1/2" (W)		
Folds to: 1 7/16" x 5 1/2"		
Codels)		
Colors:		
Black	50%, 20% Black	SKU: 5154000

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

SAFETY: Equell 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 food purposes

CAUTION: Equell 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. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. Keep this and all drugs out of reach of children.

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

ANADA 230-320, Approved by FDA

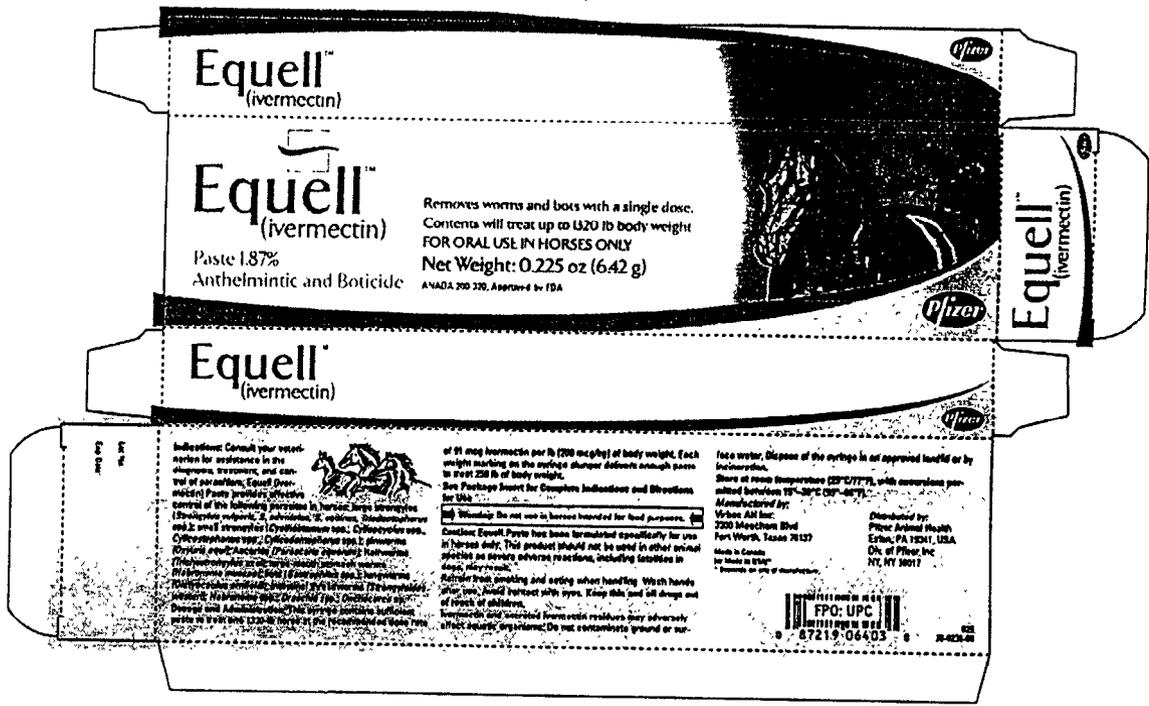
Manufactured by:
Virbac AH, Inc.
3200 Meacham Blvd
Fort Worth, Texas 76137

Distributed by:
Pfizer Animal Health
Exton, PA 19341, USA
Div of Pfizer Inc
NY, NY 10017

Made in Canada
(or Made in USA)*

* Depends on site of manufacture

Equell is a trademark of Virbac SA.



	Project Name	Part Number	Color	Date	Quantity
	Equell	20 0238 00	3	16-MAY-02	9 1/2" x 2 1/2" x 1 1/2"
	Project Number	Country	UN	Material Code	Boxes 2
	1915	The ICADY 5297A			
Editor	Michelle Brettmann	Color			800 515000
Project Front Lead	Pamela Helper				
Artist	Ron VanVelzenburg				
Proofreader	Diana Mattson				



Equell[®]

 (mectin)

NET WEIGHT 0.225g (1642 g)

(mectin)

For treatment of Large Strongids, Small Strongids, Fences, Roundworms, Bladderworms, Pinworms,
 and other parasites. See package insert for complete instructions and directions for use.

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

Caution: Keep this and all other drugs out of reach of children.

Manufactured by: Pfizer Animal Health, Kenilworth, NJ, USA

Distributed by: Pfizer Animal Health, Kenilworth, NJ, USA

Made in Canada

Made in USA

Lot No:

Exp Date:

PF-16-0000-02

 PACKAGE DESIGN & DEVELOPMENT Animal Health	Project Name Equell	Part Number 85-0238-00	Draft# 3	Date 16MAY02	Dimensions 2 3/8" x 2 1/2"	
	Project Number 1915	Country U.S.	Visual Code Bar(s)			
	Editor Michele Brettmann	Die (CAD)#	Code(s)			
	Project Team Leader Paige Hofpar	Colors:	SKU: 5154000			
	Artist Ron VanValkenburg	PMS 116	PMS 355	Black	20% Black	Pattern Varnish
Proofreader Diane Mattison						



Equell™
(ivermectin)

Paste 1.87%

Product Code:

Case Quantity: 6 displays

Lot Number

Expiration Date

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

Manufactured by:
Virbac AH Inc.
3200 Meacham Blvd
Fort Worth, Texas 76137

Distributed by:
Pfizer Animal Health
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

Made in Canada
(or Made in USA)*
* Depends on site of manufacture



024 79-0238-00



Equell™
(ivermectin)

Paste 1.87%

Product Code:

Case Quantity: 6 displays

Lot Number

Expiration Date

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

Manufactured by:
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Div. of Pfizer Inc
NY, NY 10017

Made in Canada
(or Made in USA)*
* Depends on site of manufacture



024 79-0238-00

NOTE TO USER: Swelling and itching reactions after treatment with EQVALAN (ivermectin) Paste have occurred in horses and foals heavily infested with bots. Swelling of the face and neck, and itching reactions may be observed. Consult your veterinarian about any such reactions. Never handle or prepare a product from a container that has been used for EQVALAN (ivermectin) Paste. Do not use EQVALAN (ivermectin) Paste in large numbers of horses. EQVALAN (ivermectin) Paste has been formulated specifically for use in horses only. This product should not be used in other animals as severe adverse reactions, including fatalities in dogs, may result.

WARNING: Do not use in horses intended for food purposes. EQVALAN (ivermectin) Paste has been formulated specifically for use in horses only. This product should not be used in other animals as severe adverse reactions, including fatalities in dogs, may result. Do not use in horses intended for food purposes.

Eqvalan[®]

(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
For Sale to Licensed Veterinarians



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.
For Sale to Licensed Veterinarians.

Net Wt 0.21 oz (6.08 g)

8766901

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. EQVALAN[®] (ivermectin) Paste provides effective 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. Small Strongyles including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae) — *Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicostephanus* 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) — *Dictyocephalus arnoldi*, Intestinal Threadworms (adults) — *Strongylidius weakleyi*, Summer Bots, caused by *Habronema* and *Oncophora* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm mite-larvae, *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.

Product 25874 For Oral Use in Horses Only

Eqvalan[®]

(ivermectin) Paste 1.87%

Anthelmintic and Boticide

For treatment of Large Strongyles, Small Strongyles, Pinworms, Roundworms (Large-mouth Intestinal Worms). Also see caution at bottom regarding boticide resistance. For assistance in the diagnosis, treatment and control of parasitism.

NET WT 0.21 oz (6.08 g) Made in U.S.A.

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

CAUTION: Horses that are pregnant or nursing should be treated with EQVALAN (ivermectin) Paste with caution. Wash hands after use. Avoid contact with eyes and mucous membranes.

Lot No. A
Exp. Date

MERCK
Kenilworth, N.J.
2010004

(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 anti-parasitic agent that is neither a benzimidazole nor an organophosphate. **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 food purposes.

CAUTION: 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. 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. Ivermectin and excreted ivermectin residues may adversely affect equine operations. Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

NOTE TO USER: Swelling and itching reactions after treatment with EQVALAN Paste have occurred in horses carrying heavy infections of neck threadworm (*Onchocerca sp. microstoma*). 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

issue changes may require other appropriate therapy in conjunction with ivermectin with EQVALAN (ivermectin) Paste. Fleas, ticks, and mites for their prevention, should also be considered. Consult your veterinarian if the condition does not improve.

EACH SYRINGE CONTAINS 0.21 OZ (5.98 g) IVERMECTIN PASTE
EQVALAN REG TM
MERC & CO, INC
U.S. Pat. 4,199,569 Made in U.S.A.



Merck & Co., Inc.
Kenilworth, New Jersey 07033 U.S.A.

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. EQVALAN® (ivermectin) Paste provides effective 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.; Small Strongyles including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae)—*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicocyclus* spp., *Cylicocyclus* spp.; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi*, *Ascaris* (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 immitis*; Intestinal Threadworms (adults)—*Strongylus westeri*; Summer Sores caused by *Habronema* and *Oxycerca* spp. cutaneous third-stage larvae. Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

DOSAGE AND ADMINISTRATION: The 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 anti-parasitic agent that is neither a benzimidazole nor an organophosphate.

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.

Lot No & Exp Date

83936



3 0373-258740 6



Merck & Co., Inc.
Kenilworth, New Jersey 07033 U.S.A.



U.S. Pat. 4,199,569
EQVALAN and Horse Head Logo
REG TMS MERC & CO, INC.
Made in U.S.A.

SEALED FOR SECURITY. IF BROKEN, DO NOT ACCEPT.



(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 asexual stages of *S. vulgaris*, with a single dose. EQVALAN Paste is a potent anti-parasitic agent that is neither a benzimidazole nor an organophosphate. **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 food purposes.

CAUTION: 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.

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.

Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of the syringe in an approved manner or by incineration.

NOTE TO USER: 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

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

EACH SYRINGE CONTAINS 0.21 OZ (6.06 g) IVERMECTIN PASTE

EQVALAN REG TM
MERC & CO., INC.

U.S. Pat. 4,199,569 Made in U.S.A.



Merck & Co., Inc.
Kenilworth, NJ 07033

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. EQVALAN[®] (ivermectin) Paste provides effective 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. compounds (adults and fourth-stage larvae)—*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Pinworms* (adults and fourth-stage larvae)—*Oxyuris equi*, *Ascaris* (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)—*Oxyuris equi*, Intestinal Threadworms (adults)—*Strongylus westeri*, Summer Sores caused by *Habronema* and *Oestrus* 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.

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Kenilworth, NJ 07033

Lot No & Exp Date

EQVALAN[®] (ivermectin) Paste 1.87%

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