

Date of Approval: MAY 23 2008

# FREEDOM OF INFORMATION SUMMARY

Supplemental Abbreviated New Animal Drug Application

ANADA 200-326

BIMECTIN Paste 1.87%  
(ivermectin)

Oral Paste for use in Horses

This supplement provides for the addition of claims no longer protected by marketing exclusivity; the addition of a parasite species not covered by exclusivity; revised packaging; and minor label revisions.

Sponsor:

Cross Vetpharm Group Ltd.

## FREEDOM OF INFORMATION SUMMARY

### ***1. GENERAL INFORMATION:***

- a. File Number: ANADA 200-326
- b. Sponsor: Cross Vetpharm Group Ltd.  
Broomhill Rd.  
Tallaght, Dublin 24  
Ireland
- Drug Labeler Code: 061623
- U.S. Agent: Linda M. Duple  
Bimeda, Inc.  
2836 Dolliver Park Avenue  
Lehigh, IA 50557
- 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: Each 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.
- l. Pharmacological Category: Anthelmintic and boticide
- m. 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* 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 Stronglyes** – 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.

o. Effect of Supplement:

This supplement provides for new indications for use claims no longer protected by a three-year exclusivity period that expired on April 2, 2006: **Large Strongyles** – *Craterostomum acuticaudatum*; **Small Strongyles** – *Petrovinema poculatum* and *Coronocylus* spp. including *C. coronatus*, and *C. labratus*.

The generic labeling includes an additional indication for use claim for a parasite species not protected by exclusivity, *C. labiatus*.

This supplement also provides for revised packaging and minor label revisions.

## **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.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

The sponsor demonstrated *in vivo* bioequivalence via a blood-level bioequivalence study of the generic and pioneer ivermectin pastes in horses. Refer to the original Freedom of Information (FOI) Summary dated January 19, 2005, for more detail. The pioneer product, EQVALAN the subject of Merial Ltd., NADA 134-314, was approved on May 29, 1984.

## **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 1.87%, ANADA 200-326

Syringe label; clear plastic sleeve packaging for the syringe; individual carton packaging for the syringe; display carton for syringe packaged in plastic sleeve; and display carton for syringe packaged in individual carton

Pioneer Labeling: EQVALAN Paste 1.87%, NADA 134-314

Syringe label; carton label; package outsert

Revised, March 4 2008

PANTONE 281 CVC

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 outer package for complete indications and use directions. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

ANADA# 200-326. Approved by FDA

**Net Weight: 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 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.

Manufactured by: Bimeda-MTC Animal Health Inc.  
Cambridge, Ontario, Canada N3C 2W4  
Bimectin is a Trademark of Bimeda, Inc.  
Manufactured for: Bimeda, Inc.  
Le Sueur, MN 56058



LOT XXXXX  
EXP XX XXX

2" X 3.5"

100% Size

200% Size for text only

VARNISH LINE

**Bimectin™** For Oral Use  
in Horses Only  
**(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 outer package for complete indications and use directions. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

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Le Sueur, MN 56058

REV.03.08  
8BIM00X



LOT XXXXX  
EXP XX XXX

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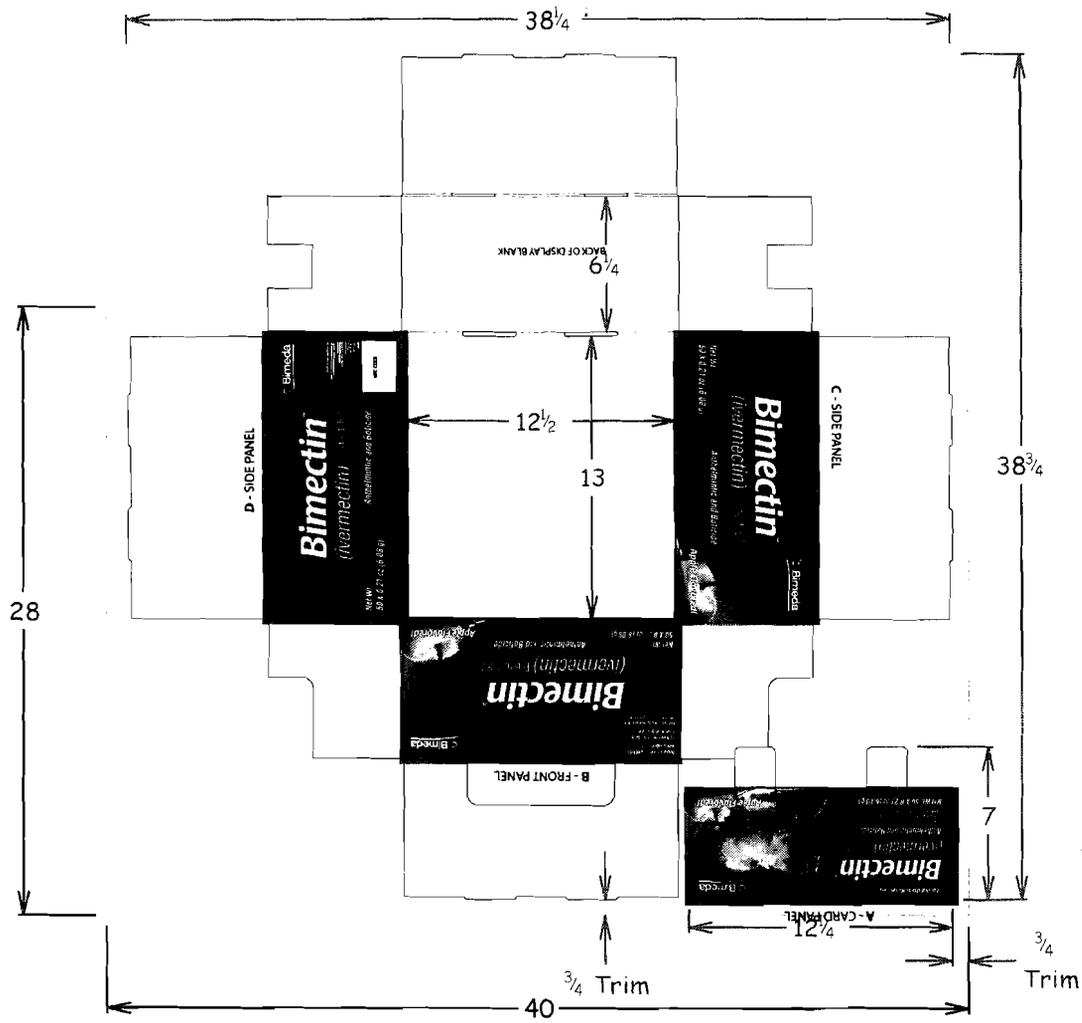




Illustration

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MAR 20 2008



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 MAR 20 2008

# D - SIDE PANEL



# ***Bimectin***<sup>TM</sup> ***(ivermectin)*** Paste 1.87%

Bimectin is a Trademark of Bimeda, Inc.  
Bimeda, Inc. and Bimeda-MIC Animal Health Inc.  
are Divisions of Cross Veterinary Group Ltd.  
Manufactured by  
Bimeda-MIC Animal Health Inc.  
Parsippany, Ontario, Canada N2C 2W4  
M. Health 147/06  
Bimeda, Inc.  
147/06-147/06-05  
147/06-147/06-05  
147/06-147/06-05  
147/06-147/06-05

**Net Wt.**  
**50 X 0.21 oz (6.08 g)**

***Anthelmintic and Boticide***



100% Scale

MAR 20 2008  
000523

C - SIDE PANEL

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 **Bimeda**

# ***Bimectin***<sup>TM</sup>

*(ivermectin)* Paste 1.87%

*Net Wt.*  
50 X 0.21 oz (6.08 g)

*Anthelmintic and Boticide*

*Apple Flavored!*

100% Scale

MAR 25 2008

00019

*Net Wt.*  
50 X 0.21 oz

# A - CARD PANEL

For Oral Use In Horses Only

 **Bimeda**

# **Bimectin**<sup>TM</sup> (ivermectin) Paste 1.87%

**Anthelmintic and Boticide**

*Removes worms and bots with a single dose.  
Contents will treat up to 1250 lb body weight  
ANADA# 200-326. Approved by FDA*

**Net Wt. 50 X 0.21 oz (6.08 g)**



**Apple Flavored!**

100% Scale

MAR 20 2008

000517

*Removes worms and  
with a single dose.*

*Contents will treat  
1250 lb body weight*

# B - FRONT PANEL

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

 **Bimeda**

# ***Bimectin***<sup>TM</sup> *(ivermectin)* Paste 1.87%

Net Wt.  
50 X 0.21 oz (6.08 g)

*Anthelmintic and Boticide*

100% Scale

*Apple Flavored!*



MAR 2 J 2008

000315

NET WT.  
50 X 0.21 oz

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 (6.08 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.  
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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

MERIAL

(ivermectin) Paste 1.87%

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

NADA 134-314, Approved by the FDA



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

**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.

**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 sensitive tissue changes may require other appropriate therapy in conjunction with treatment with EQVALAN Paste. Reinfestation and measures for its prevention should also be considered. Consult your veterinarian if the condition does not improve.

Environmental Safety: Ivermectin and excised 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.

a MSDS, contact Merial at 1-888-637-4251.

Information: To report adverse reactions in users, to obtain more information, or to obtain eyes. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. Retain from smoking and eating when handling. Wash hands after use. Avoid contact with Not for use in humans. Keep this and all drugs out of reach of children.



**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) - *Coronocylus* spp. including *C. coronatus*, *C. labiatus* and *C. labratus*, *Cyathostomum* spp. including *C. cabinatum* and *C. pateratum*, *Cylicocylus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus* and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calceatus*, *C. galki*, *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 armfieldi*; **Intestinal Threadworms** (adults) - *Strongyloides westeri*; **Summer Sores** caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Anchocera* 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

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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.

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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

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summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with EQVALAN (ivermectin) Paste. Reinfestation, 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

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*Anthelmintic and Boticide*

*(ivermectin) Paste 1.87%*

# **Bimectin™**

Bimeda



*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*

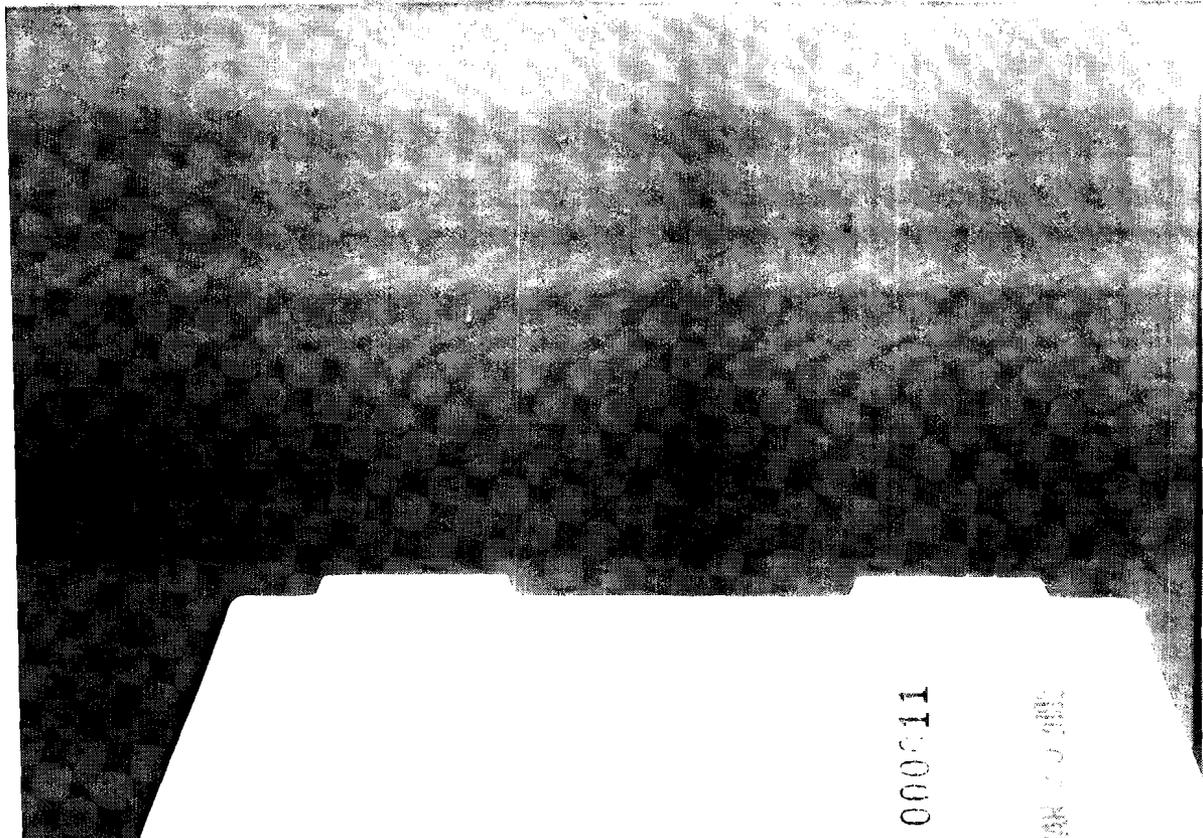
# **Bimectin™**

*(ivermectin) Paste 1.87%*

*Net Wt.*

*12 X 0.21 oz (6.08 g)*

*Anthelmintic and Boticide*



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MAK 10/01

*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.  
12 X 0.21 oz (6.08 g)*

# ***Bimectin***<sup>TM</sup> ***(ivermectin)*** Paste 1.87%

***Anthelmintic and Boticide***

***Apple Flavored***