

HFA 305

Date of Approval: \_\_\_\_\_

**FREEDOM OF INFORMATION SUMMARY  
SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG  
APPLICATION (ANADA)**

**ANADA 200-246**

**For Over-The-Counter Use of  
Pyrantel Pamoate Equine Anthelmintic Suspension  
(pyrantel pamoate)  
50 mg pyrantel base as pyrantel pamoate per mL**

**Equine Anthelmintic**

Indications for use: For the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles in horses and ponies.

**Sponsored by:**

**Phoenix Scientific, Inc.  
3915 South 48<sup>th</sup> Street Terrace  
St. Joseph, MO 64503**

ANADA 200-246

FOIS

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

- a. File Number: ANADA 200-246
- b. Sponsor: Phoenix Scientific, Inc.  
3915 S. 48<sup>th</sup> Street Terrace  
St. Joseph, MO 64503  
  
Drug Labeler Code: 059130
- c. Established Name: Pyrantel pamoate
- d. Proprietary Name: Pyrantel Pamoate Equine Anthelmintic Suspension
- e. Dosage Form: Liquid Suspension
- f. How Supplied: 16 oz and 32 oz HDPE bottles
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Each mL contains 50 mg pyrantel base as pyrantel pamoate
- i. Route of Administration: Oral
- j. Species/Class: Horses and Ponies
- k. Recommended Dosage: Administer 3 mg pyrantel base per pound of body weight [6 mL Pyrantel Pamoate per 100 lb body weight]. Administer by means of a dose syringe or by mixing into the feed. It is recommended that severely debilitated animals not be treated with this preparation.
- l. Pharmacological Category: Anthelmintic
- m. Indications: For the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles in horses and ponies.
- n. Pioneer Product: Pamoban<sup>TM</sup> Horse Wormer; pyrantel pamoate; NADA 091-739; Pfizer, Inc.

- o. Effect of Supplement: Pyrantel Pamoate Equine Anthelmintic Suspension for horses is a supplement to the original ANADA 200-246 for the prescription product Anthelban V (pyrantel pamoate). This supplement provides for the over-the-counter use of Pyrantel Pamoate Equine Anthelmintic Suspension, an identical formulation to Anthelban V labeled for the same conditions of use, except administration by stomach tube.

## **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 (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 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. The requirements for the *in vivo* blood level bioequivalence study may be waived for certain generic products. Upon approval, an ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. ANADAs for drug products for food-producing animals will generally be required to include *in vivo* bioequivalence and tissue residue studies. If a waiver of the *in vivo* bioequivalence and/or tissue residue study is granted for a food animal product, then the withdrawal period established for the pioneer product will be assigned to the generic product. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on June 25, 1997, from the requirement of an *in vivo* bioequivalence study for Anthelban V. The waiver applies equally to the OTC label for the identical formulation, Pyrantel Pamoate Equine Anthelmintic Suspension. This product is a generic copy of Pfizer Inc.'s Pamoban™ Horse Wormer (OTC), NADA 091-739 (50 mg/mL pyrantel base as pyrantel pamoate). The generic and pioneer products contain the same active ingredients and are liquid suspensions intended for use in horses by the oral route of administration. The pioneer product, Pamoban™ Horse Wormer (OTC), sponsored by Pfizer Inc. (NADA 091-739), was approved on July 6, 1976.

## **3. HUMAN SAFETY:**

This drug is indicated for use only in horses and ponies, which are non-food animals. Since this generic animal drug is not intended for food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Labeling contains adequate caution/warning statements. Human Warnings are provided on the product label as follows: "Keep out of reach of children." "Not for horses or ponies intended for food."

**4. AGENCY CONCLUSIONS:**

This abbreviated new animal drug application (ANADA) filed 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 Pyrantel Pamoate Equine Anthelmintic Suspension, when used under its proposed conditions of use, is safe and effective for its labeled indications.

**5. ATTACHMENTS:**

Pioneer Labeling for NADA 091-739:

Pamoban<sup>TM</sup> Horse Wormer (50 mg/mL pyrantel base as pyrantel pamoate)  
1 – Bottle Label (60 mL); 1 – Box Label

Generic Labeling for ANADA 200-246:

Pyrantel Pamoate Equine Anthelmintic Suspension (50 mg/mL pyrantel base as pyrantel pamoate)  
1 – Package Insert; 1 – Bottle Label (946 mL); 1 – Bottle Label (473 mL)

264

**ACTIVE INGREDIENT**  
50 mg of pyrantel base as  
pyrantel pamoate per ml

**DOSAGE**  
Administer 6 ml (1/4 oz.) of Pamoban  
per 100 pounds of body weight.

**DIRECTIONS FOR USE**  
Pamoban may be administered by  
means of a dose syringe or by  
mixing into the feed.

**Dose Syringe**—Draw the  
appropriate dosage of Pamoban  
into a dose syringe and administer  
to the animal. Do not expose  
Pamoban to direct sunlight.  
**Feed**—Mix the appropriate dosage  
of Pamoban in the normal grain  
ration. Fasting of animals prior to  
or following treatment is not  
required.

**SHAKE WELL BEFORE USE**  
MADE IN U.S.A.

(pyrantel pamoate) TM  
**Pamoban  
Horse Wormer**

**suspension**

for the removal and control of  
mature infections of large  
strongyles (*Strongylus vulgaris*,  
*S. edentatus*, *S. equinus*); small  
strongyles (*Trichonema* sp.,  
*Triodontophorus*); pinworms  
(*Oxyuris*); and large roundworms  
(*Parascaris*) in horses and  
ponies.

Net Contents: 2 oz. (60 ml)

**WARNING**  
NOT FOR HORSES OR PONIES  
INTENDED FOR FOOD.  
KEEP OUT OF REACH OF  
CHILDREN.

**CAUTION**  
CONSULT YOUR VETERINARIAN  
FOR ASSISTANCE IN THE  
DIAGNOSIS, TREATMENT, AND  
CONTROL OF PARASITISM.

It is recommended that severely  
debilitated animals not be  
treated with this preparation.

**RECOMMENDED STORAGE**  
STORE BELOW 30°C. (86°F.)



**pfizer**

Distributed by  
**Pfizer** AGRICULTURAL DIVISION  
NEW YORK, N.Y. 10017

**Pamoban  
Horse Wormer  
Suspension**

#408

**Pamoban  
Horse Wormer  
Suspension**

**DOSAGE**  
Administer 6 ml (1/4 oz.) of Pamoban  
per 100 pounds of body weight.

**DIRECTIONS FOR USE**  
Pamoban may be administered by  
means of a dose syringe or by  
mixing into the feed.

**Dose Syringe**—Draw the appropriate  
dosage of Pamoban into a dose  
syringe and administer to the  
animal. Do not expose Pamoban  
to direct sunlight.

**Feed**—Mix the appropriate dosage of  
Pamoban in the normal grain ration.  
Fasting of animals prior to or  
following treatment is not required.

**SHAKE WELL BEFORE USE**

**WARNING**  
NOT FOR HORSES OR PONIES  
INTENDED FOR FOOD.  
KEEP OUT OF REACH OF CHILDREN.

**CAUTION**  
CONSULT YOUR VETERINARIAN FOR  
ASSISTANCE IN THE DIAGNOSIS,  
TREATMENT, AND CONTROL OF  
PARASITISM.

It is recommended that severely  
debilitated animals not be  
treated with this preparation.



Distributed by  
**Pfizer** AGRICULTURAL DIVISION  
NEW YORK, N.Y. 10017  
MADE IN U.S.A.

**INDICATIONS FOR USE**

For the removal and control of  
mature infections of large  
strongyles (*Strongylus vulgaris*,  
*S. edentatus*, *S. equinus*); small  
strongyles (*Trichonema* sp.,  
*Triodontophorus*); pinworms  
(*Oxyuris*); and large roundworms  
(*Parascaris*) in horses and ponies.

**ACTIVE INGREDIENT**  
50 mg of pyrantel base as  
pyrantel pamoate per ml

See Back Panel For Complete  
Use Directions.

**RECOMMENDED STORAGE**  
STORE BELOW 30°C. (86°F.)

(pyrantel pamoate) TM  
**Pamoban  
Horse  
Wormer**

**suspension**

for the removal and control of  
mature infections of large  
strongyles (*Strongylus vulgaris*,  
*S. edentatus*, *S. equinus*); small  
strongyles (*Trichonema* sp.,  
*Triodontophorus*); pinworms  
(*Oxyuris*); and large roundworms  
(*Parascaris*) in horses and ponies.  
Active ingredient  
50 mg of pyrantel base as pyrantel  
pamoate per ml

Net Contents: 2 oz. (60 ml)

**pfizer**

**pfizer**

10-2834-00-0

**Pamoban  
Horse Wormer  
Suspension**

**pfizer**

**Pamoban**

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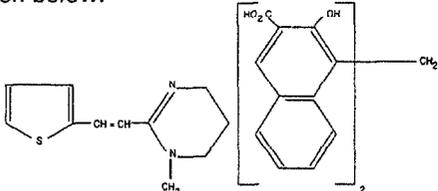
ANADA 200-246, Approved by FDA

# Pyrantel Pamoate

## Equine Anthelmintic Suspension

Pyrantel Pamoate is a suspension of pyrantel pamoate in a palatable vanilla-flavored vehicle. Each mL contains 50 mg of pyrantel base as pyrantel pamoate.

Pyrantel pamoate is a compound belonging to a family classified chemically as tetrahydropyrimidines. It is a yellow, water-insoluble crystalline salt of the tetrahydropyrimidine base and pamoic acid containing 34.7% base activity. The chemical structure and name are given below:



(E)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl] pyrimidine 4, 4' methylenebis [3-hydroxy-2-naphthoate] (1:1)

### INDICATIONS FOR USE

For the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles in horses and ponies.

### DOSAGE AND TREATMENT

Administer 3 mg pyrantel base per pound of body weight (6 mL Pyrantel Pamoate per 100 lb body weight).

For maximum control of parasitism, it is recommended that foals (2-8 months of age) be dosed every 4 weeks. To minimize potential hazard that the mare may pose to the foal, she should be treated 1 month prior to anticipated foaling date followed by retreatment 10 days to 2 weeks after birth of foal. Horses over 8 months of age should be routinely dosed every 6 weeks.

### DIRECTIONS FOR USE

Pyrantel Pamoate may be administered by means of a dose syringe or by mixing into the feed.

### DIRECTIONS FOR USE (continued)

**Dose Syringe** - Draw the appropriate dosage of Pyrantel Pamoate into a dose syringe and administer to the animal. Do not expose Pyrantel Pamoate to direct sunlight.

**Feed** - Mix the appropriate dosage of Pyrantel Pamoate in the normal grain ration. Fasting of animals prior to or following treatment is not required.

**CAUTION:** THIS PRODUCT IS A SUSPENSION AND AS SUCH WILL SEPARATE. TO INSURE UNIFORM RE-SUSPENSION AND TO ACHIEVE PROPER DOSAGE, IT IS EXTREMELY IMPORTANT THAT THE PRODUCT BE SHAKEN AND STIRRED THOROUGHLY BEFORE EVERY USE.

### EFFICACY

Critical (worm-count) studies in horses demonstrated that pyrantel pamoate administered at the recommended dosage was efficacious against mature infections of *Strongylus vulgaris* (>90%), *S. edentatus* (69%), *S. equinus* (>90%), *Oxyuris equi* (81%), *Parascaris equorum* (>90%), and small strongyles (>90%).

### SAFETY

Pyrantel Pamoate is well tolerated by horses and ponies of all ages. No adverse drug response was observed when dose rates up to 60 mg pyrantel base per pound of body weight were administered by stomach tube nor when 3 mg base per pound was given by intratracheal injection. The reproductive performance of pregnant mares and stud horses dosed with Pyrantel Pamoate has not been affected.

**WARNING:** NOT FOR HORSES OR PONIES INTENDED FOR FOOD. KEEP OUT OF REACH OF CHILDREN.

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. It is recommended that severely debilitated animals not be treated with this preparation.

**RECOMMENDED STORAGE:** Store below 86°F (30°C).



Manufactured by  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

500011

Iss. 2-02

**DIRECTIONS FOR USE:** Pyrantel Pamoate may be administered by means of a dose syringe or by mixing into the feed.

**CAUTION: THIS PRODUCT IS A SUSPENSION AND AS SUCH WILL SEPARATE. TO INSURE UNIFORM RE-SUSPENSION AND TO ACHIEVE PROPER DOSAGE, IT IS EXTREMELY IMPORTANT THAT THE PRODUCT BE SHAKEN AND STIRRED THOROUGHLY BEFORE EVERY USE.**

**Dose Syringe** - Draw the appropriate dosage of Pyrantel Pamoate into a dose syringe and administer to the animal. Do not expose Pyrantel Pamoate to direct sunlight.

**Feed** - Mix the appropriate dosage of Pyrantel Pamoate in the normal grain ration. Fasting of animals prior to or following treatment is not required.



Manufactured by  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

NDC 59130-642-18

# Pyrantel Pamoate

## Equine Anthelmintic Suspension

**Active Ingredient: 50 mg of pyrantel base as pyrantel pamoate per mL**

**SHAKE WELL BEFORE USE**

**KEEP OUT OF REACH  
OF CHILDREN**

ANADA 200-246, Approved by FDA

**NET CONTENTS: 946 mL (1 Qt)**

**AmTech**®  
Group, Inc.

**INDICATIONS FOR USE:** For the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles in horses and ponies.

**DOSAGE:** Administer 3 mg pyrantel base per pound of body weight [6 mL Pyrantel Pamoate per 100 lb body weight]. It is recommended that severely debilitated animals not be treated with this preparation.

**WARNING: NOT FOR HORSES OR PONIES INTENDED FOR FOOD. KEEP OUT OF REACH OF CHILDREN.**

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

**READ ACCOMPANYING INFORMATION**

**RECOMMENDED STORAGE:  
STORE BELOW 86°F (30°C)**



500011

Iss. 02-02

Lot No.

Exp. Date

**DIRECTIONS FOR USE:**

Pyrantel Pamoate may be administered by means of a dose syringe or by mixing into the feed.

**CAUTION: THIS PRODUCT IS A SUSPENSION AND AS SUCH WILL SEPARATE. TO INSURE UNIFORM RE-SUSPENSION AND TO ACHIEVE PROPER DOSAGE, IT IS EXTREMELY IMPORTANT THAT THE PRODUCT BE SHAKEN AND STIRRED THOROUGHLY BEFORE EVERY USE.**

**Dose Syringe** - Draw the appropriate dosage of Pyrantel Pamoate into a dose syringe and administer to the animal. Do not expose Pyrantel Pamoate to direct sunlight.

**Feed** - Mix the appropriate dosage of Pyrantel Pamoate in the normal grain ration. Fasting of animals prior to or following treatment is not required.

Manufactured by  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

TAKE TIME  OBSERVE LABEL DIRECTIONS



NDC 59130-642-06

# Pyrantel Pamoate

**Equine Anthelmintic Suspension**

**Active Ingredient: 50 mg of pyrantel base as pyrantel pamoate per mL**

**SHAKE WELL BEFORE USE  
KEEP OUT OF REACH OF CHILDREN**

ANADA 200-246, Approved by FDA

**NET CONTENTS: 473 mL (1 Pint)**

**AmTech**®  
Group, Inc.

**INDICATIONS FOR USE:** For the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles in horses and ponies.

**DOSAGE:** Administer 3 mg pyrantel base per pound of body weight [6 mL Pyrantel Pamoate per 100 lb body weight]. It is recommended that severely debilitated animals not be treated with this preparation.

**WARNING: NOT FOR HORSES OR PONIES INTENDED FOR FOOD. KEEP OUT OF REACH OF CHILDREN.**

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

**READ ACCOMPANYING INFORMATION**

**RECOMMENDED STORAGE:  
STORE BELOW 86°F (30°C)**

500011

Iss. 2-02

Lot No.

Exp. Date