

HFV-305

**Date of Approval:** JAN 22 2003

**FREEDOM OF INFORMATION (FOI) SUMMARY**

**Pyrantel Pamoate Paste**

**Equine Anthelmintic Paste**

**ANADA 200-342**

**Phoenix Scientific, Inc.**

**3915 South 48<sup>th</sup> Street Terrace**

**St. Joseph, MO 64503**

**ANADA 200-342**

**FOIS**

1. GENERAL INFORMATION

ANADA : 200-342

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

Drug Labeler Code 059130

Generic Name: Pyrantel Pamoate Paste

Trade Name: Pyrantel Pamoate Paste

Dosage Form: Oral Paste

How Supplied: 15.9 mL in 36 mL syringe

How Dispensed: OTC

Amount of Active Ingredients: 19.13%

Route of Administration Oral

Species: Horses

Labeled Dosage: 3 mg pyrantel base per pound of body weight

Indications for Use: Pyrantel Pamoate Paste is indicated for the removal and control of mature infections of the following parasites:

**Large Strongyles:** *Strongylus vulgaris*  
*S. edentatus* *S. equinus*

**Small Strongyles**

**Pinworms** *Oxyuris equi*

**Large Roundworms**  
*Parascaris equorum*

Pioneer Product: Strongid® Paste (Pyrantel Pamoate)  
(Listed Product): NADA 129-831 (Pfizer Animal Health)

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 shows 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 2000).

This ANADA approval is based on a demonstration that the generic product is bioequivalent to the pioneer product.

**Bioequivalence Study  
PSI -0690-00E-005**

**Title:** Controlled Bioequivalence Study of Generic Pyrantel Pamoate Paste (PSI) and Strongid® Paste in Horses

**Study Location(s):** East Tennessee Clinical Research, Inc.  
1717 Western Avenue  
Knoxville, Tennessee 37921

Copper Ridge Farm  
80 Copper Ridge Farm Road  
Rockwood, Tennessee 37854

**Summary:** Animals with historical evidence of naturally acquired infections of *Strongylus edentatus* and *Cyathostomum catinatum* were observed and acclimated for 14 days prior to study start. After meeting entrance criteria, 36 horses were ranked in decreasing order by body weight. Each three consecutive horses comprised a replicate set (for a total of 12 replicates). Within each replicate, treatments were assigned completely at random and were equally represented. Animals assigned to treatment group 1 received the test article (PSI generic

pyrantel pamoate paste) at 6.6 mg pyrantel base per kilogram body weight. Animals assigned to treatment group 2 received the positive control (Pfizer Strongid® Paste) at 6.6 mg/kg. Animals assigned to treatment group 3 were untreated controls.

Clinical observations were conducted prior to treatment and between 6-8 hours after treatment on day 0. Thereafter, observations for general health and adverse events were conducted once daily until necropsy on Days 10, 11 and 12. The various organs of the large intestine were separated, opened longitudinally, and the contents were collected in a large container. All attached parasites (e.g., large strongyles) were collected and placed in labeled containers of 10% formalin. The contents of the organs and washings were combined and mixed thoroughly. Duplicate 10% and duplicate 1% aliquots of intestinal contents were collected and preserved with formalin for enumeration of adult *Strongylus edentatus* and *Cyathostomum catinatum*, respectively.

Adult *S. edentatus* were found in all 12 horses of treatment group 3 (untreated controls). The percent efficiency of the treatment group 1 (test article) was calculated as 90%, and the percent efficiency of treatment group 2 (positive control) was calculated as 92%.

Adult *C. catinatum* were found in 11 of 12 horses of treatment group 3 (untreated controls). The percent efficiency of the treatment group 1 (test article) was calculated as 99.9%, and the percent efficiency of treatment group 2 (positive control) was calculated as 100%.

As both the test article (PSI Pyrantel Paste) and the positive control (Pfizer Strongid® Paste) were found to be greater than or equal to 90% effective against both *S. edentatus* and *C. catinatum*, no further statistical evaluation was necessary. Phoenix Scientific Inc.'s Pyrantel Pamoate Paste and Pfizer's Strongid® Paste are considered bioequivalent when administered as an intended oral dosage of 6.6 mg pyrantel base per kg body weight under controlled conditions.

3. **HUMAN SAFETY**

**Human Safety Relative to Food Consumption:**

None required as Pyrantel Pamoate Paste is intended for use only in horses. The labeling includes the statement, **“WARNING: NOT FOR USE IN HORSES INTENDED FOR FOOD”**.

**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, Pyrantel Pamoate Paste, were established by demonstration of bioequivalence to the pioneer product, Strongid® Paste (NADA 129-831, Pfizer).

This generic product and the pioneer product have identical labeling indications for 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(n) of the Act and demonstrates that Pyrantel Pamoate Paste is safe and effective for its labeled indications when used under its proposed conditions of use.

5. **Attachments:**

1. **Generic labeling:**

Package Insert-onsert  
Syringe Label-18.8g (15.0mL)  
Display Label-6x18.8g (15.9mL)

2. **Pioneer Labeling**

Package Insert  
Syringe Label-20 mL (23.6g)  
Carton Label

NDC 59130-730-54

### PYRANTEL PAMOATE PASTE

#### Equine Anthelmintic

Active Ingredients: Each syringe contains 3.60 grams pyrantel base in 18.8 grams of paste.

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

**NOTE:** Position screw-gauge over appropriate mark on plunger. Each milliliter contains 226 milligrams pyrantel base as pyrantel pamoate. It is recommended that severely debilitated animals not be treated with this preparation.

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

**STORAGE:** STORE AT CONTROLLED ROOM TEMPERATURE 20°-25°C (68°-77°F). REFER TO PACKAGE INSERT FOR COMPLETE USE DIRECTIONS FOR ORAL USE IN HORSES ONLY.

**WARNING:** NOT FOR USE IN HORSES INTENDED FOR FOOD. KEEP OUT OF REACH OF CHILDREN.

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

**STORAGE:** STORE AT CONTROLLED ROOM TEMPERATURE 20°-25°C (68°-77°F). REFER TO PACKAGE INSERT FOR COMPLETE USE DIRECTIONS FOR ORAL USE IN HORSES ONLY.

800002 Iss. 7-00

ANADA 200-342, Approved by FDA

**NET CONTENTS: 18.8g (15.9mL)**

AmTech Group, Inc.

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

NDC 59130-730-54

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800002 Iss. 7-00

ANADA 200-342, Approved by FDA

**NET CONTENTS: 18.8g (15.9mL)**

AmTech Group, Inc.

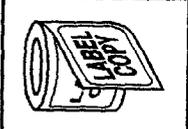
Manufactured by Phoenix Scientific, Inc. St. Joseph, MO 64503

### CUSTOMER PROOF • CHECK CAREFULLY!

Customer: PHOENIS SCIENTIFIC P.O. #: STEPHANIE

CYREL #: 28418 (LW) Date Sent: 5/18/00 5/26/00 11/21/00 12/6/00 12/13/00 4/25/02

LABEL:	AM TECH PYRANTEL PAMOATE 20ML	UNWIND #:	4
SIZE:	3.5" X 3.0"		
VARNISH:	<input checked="" type="checkbox"/> YES <input checked="" type="checkbox"/> PATTERN <input type="checkbox"/> FLOOD <input type="checkbox"/> NO		
COLORS:	1797 red    black    water varn.		



**Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks. Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.**

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

**PYRANTEL PAMOATE PASTE**  
**Equine Anthelmintic**  
 ANADA 200-342, Approved By FDA  
 Net Contents: 18.8g (15.9mL)

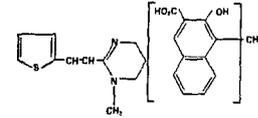



PYRANTEL PAMOATE PASTE is a yellow-green paste containing 55.1% w/w pyrantel pamoate in an inert vehicle. Each syringe contains 3.60 grams pyrantel base in 18.8 grams paste. Each milliliter contains 225 milligrams pyrantel base as pyrantel pamoate.

**READ ENTIRE BROCHURE CAREFULLY BEFORE USING THIS PRODUCT**

**COMPOSITION**

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.



**Chemical Name:** (E)-1,4,5,6-tetrahydro-1-methyl-2-(2-(2-thienyl)-vinyl)-pyrimidine 4,4'-methylenebis[3-(4-hydroxy-2-naphtholate)] (1:1)

**INDICATIONS FOR USE**

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

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

**DOSAGE AND TREATMENT**

PYRANTEL PAMOATE PASTE is to be administered as a single oral dose of 3 milligrams pyrantel base per pound of body weight. The syringe has four weight mark increments. Each weight mark indicates the recommended dose for 300 pounds of body weight.

DOSAGE		
Body Weight Range	Volume	mg Pyrantel Base
up to 300 lb	1/4 syringe	900 mg
301 to 600 lb	1/2 syringe	1800 mg
601 to 900 lb	3/4 syringe	2700 mg
901 to 1200 lb	1 full syringe	3600 mg

**NOTE:** Position screw-gauge over appropriate mark on plunger. Each milliliter contains 225 milligrams pyrantel base as pyrantel pamoate.

For maximum control of parasitism, it is recommended that foals (2-5 months of age) be dosed every 4 weeks. To minimize the potential source of infection that the mare may pose to the foal, the mare should be treated 1 month prior to anticipated foaling date followed by re-treatment 10 days to 2 weeks after birth of foal. Horses and ponies over 8 months of age should be routinely dosed every 6 weeks.

**ADMINISTRATION**

After removing the cap, the paste should be deposited on the dorsum of the tongue introduce the nozzle and of the syringe at the corner of the mouth. Direct the syringe backwards and depress the plunger to

deposit the paste onto the tongue. Given in this manner, it is unlikely that rejection of the paste will occur. Raising the horse's head sometimes assists in the swallowing process. When only part of the paste has been used, replace the cap on the syringe nozzle.

**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* (88%), *S. equinus* (>90%), *Oxyuris equi* (81%), *Parascaris equorum* (>90%), and small strongyles (>90%).

**WARNING: NOT FOR USE IN HORSES INTENDED FOR FOOD. KEEP OUT OF REACH OF CHILDREN.**

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

**STORE AT A CONTROLLED ROOM TEMPERATURE 20°-25°C (68°-77°F)**

B00002

Iss 5-00



Manufactured by  
 Phoenix Scientific, Inc  
 St Joseph, MO 64503

**CUSTOMER PROOF • CHECK CAREFULLY!**

Customer: AM-TECH P.O. #: STEPHANIE  
 CYREL #: 28419 (ts) Date Sent: 5/18/00 11/28/00 12/18/00 4/25/02 04/25/02

LABEL: pyrantel pamoate UNWIND #: \_\_\_\_\_  
 SIZE: 2.25 x 6.5  
 VARNISH:  YES  PATTERN  FLOOD  
 NO  
 COLORS: blk 1797 red

Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks. Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

NDC 59130-730-54

Contents of each syringe will treat up to 1200 lb body weight  
ANADA 200-342, Approved by FDA  
Net Wt: 12 x 18.8 g (15.9 mL)



RIGHT PANEL

**PYRANTEL PAMOATE PASTE**

Equine Anthelmintic  
FOR ORAL USE IN HORSES ONLY

Net Wt: 12 x 18.8 g (15.9 mL)

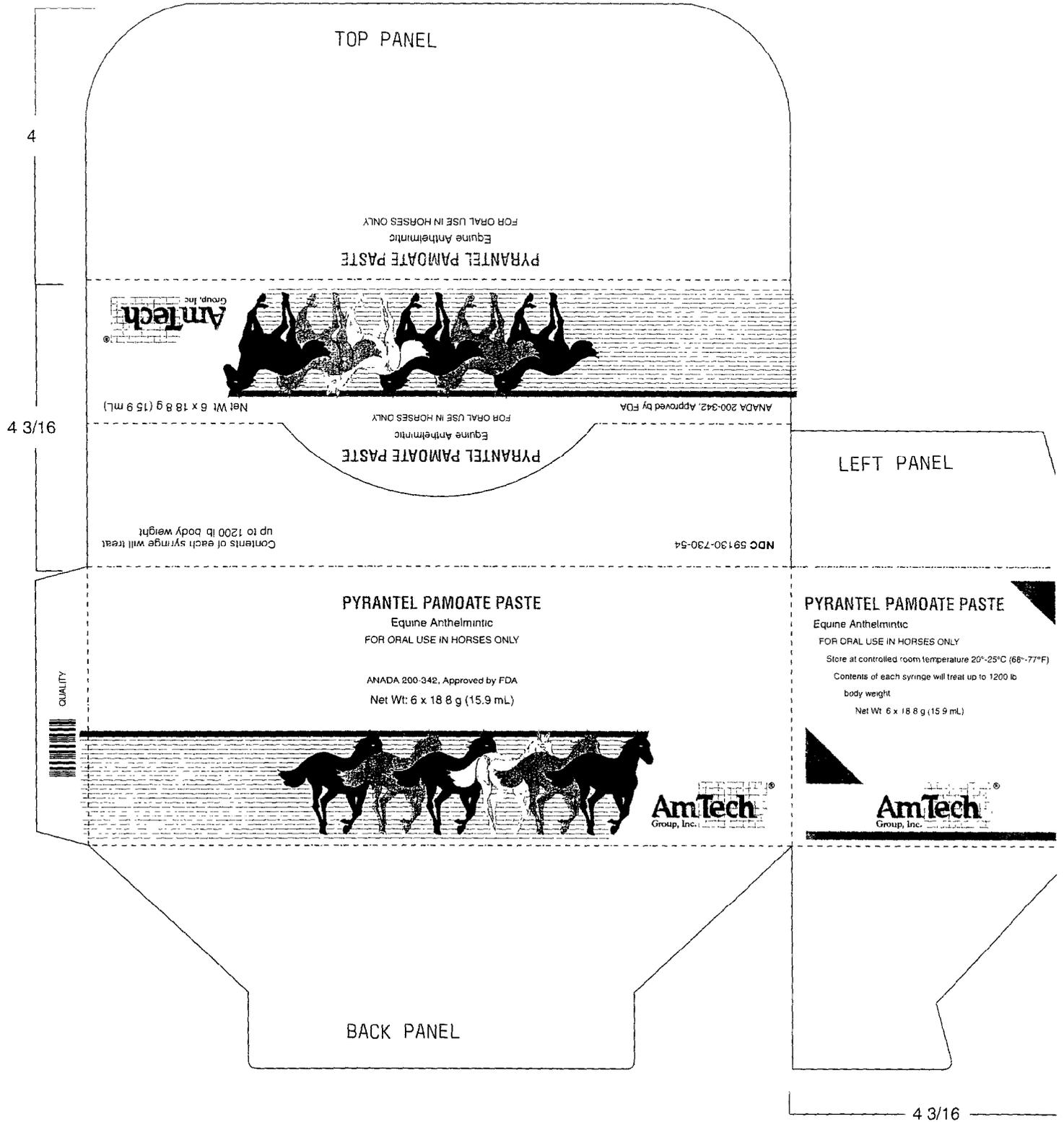
Manufactured by  
Innovative Scientific, Inc.  
St. Joseph, MO 64503

Lot No  
Exp. Date

**AmTech**  
Group, Inc.

800002  
Iss 4-02

FRONT PANEL



**Strongid® Paste**  
(pyrantel pamoate)  
Equine Anthelmintic

**Strongid® Paste**  
(pyrantel pamoate)  
Equine Anthelmintic  
For animal use only  
**Net Weight: 20 mL (23.6 g)**

The safe and effective horse and foal dewormer that is  
easy to use.  
Each 20-ml syringe contains 3.6 grams of pyrantel base in  
23.6 grams of paste.



NADA #128-831, Approved by FDA

*Jans*  
CAD#0847M

**Strongid® Paste**  
(pyrantel pamoate)  
Equine Anthelmintic



OBSERVE LABEL DIRECTIONS



TAKE TIME

Distributed by:  
**Animal Health**

Exton, PA 19341, USA  
Div. of Pfizer Inc  
NY, NY 10017



003 20-7973-01  
Made in USA

The syringe has 4 weight mark increments. Each weight

**mg Pyrantel Base**

- 900 mg
- 1800 mg
- 2700 mg
- 3600 mg

**Volume**

- 1/4 syringe (5 mL)
- 1/2 syringe (10 mL)
- 3/4 syringe (15 mL)
- 1 full syringe (20 mL)

pyrantel base as pyrantel pamoate. To minimize the potential source of

**Dosage.** Administer as a single, oral dose of 3 mg pyrantel base per lb of body weight. The syringe has 4 weight mark increments. Each weight mark indicates the recommended dose for 300 lb of body weight.

**Body Weight Range**

- up to 300 lb
- 301-600 lb
- 601-900 lb
- 901-1200 lb

**Note:** Position screw-gauge over appropriate mark on plunger. Each mL contains 180 mg pyrantel base as pyrantel pamoate. To minimize the potential source of infection that the mare may pose to the foal, the mare should be treated 1 month prior to anticipated foaling date followed by retreatment 10 days to 2 weeks after birth of foal. Horses and ponies over 8 months of age should be routinely dosed every 6 weeks.

**Note:** Position screw-gauge over appropriate mark on plunger. Each mL contains 180 mg pyrantel base as pyrantel pamoate. To minimize the potential source of infection that the mare may pose to the foal, the mare should be treated 1 month prior to anticipated foaling date followed by retreatment 10 days to 2 weeks after birth of foal. Horses and ponies over 8 months of age should be routinely dosed every 6 weeks.

**Strongid® Paste**  
(pyrantel pamoate)  
Equine Anthelmintic

**See Package Insert for Complete Use Directions**

**Warnings:** Not for use in horses intended for food. Keep out of reach of children. For oral use only.

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

**Store at Controlled Room Temperature 15°-30°C (59°-86°F)**

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

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**PROOF OF PURCHASE**

129-831#5c  
10/1/00

COPY

OK Rev

### Strongid® Paste

1156

(pyrantel pamoate)

Equine Anthelmintic

Net Contents: 20 mL (23.6 g)

For animal use only

NADA #129-831, Approved by FDA

**Active Ingredients:** Each 20-mL syringe contains 3.6 g pyrantel base in 23.6 g of paste.

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

**Dosage:** Administer as a single oral dose of 3 mg pyrantel base per lb of body weight. The syringe has 4 weight mark increments. Each weight mark indicates the recommended dose for 300 lb of body weight.

Body Weight Range	Volume	mg Pyrantel Base
up to 300 lb	1/4 syringe (5 mL)	900 mg
301-600 lb	1/2 syringe (10 mL)	1800 mg
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901-1200 lb	1 full syringe (20 mL)	3600 mg

**Note:** Position screw-gauge over appropriate mark on plunger. Each mL contains 180 mg pyrantel base as pyrantel pamoate.

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

**Warnings:** Not for use in horses intended for food. Keep out of reach of children.

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

**Recommended Storage:** Store at room temperature 15°-30°C (59°-86°F).

Refer to Package Insert for Complete Use Directions



Distributed by  
**Animal Health**  
Kenilworth, PA 19041, USA  
Div. of Pfizer Inc.  
NY, NY 10017

003 85-7973-01  
Made in USA

Lot

Exp

COPY

12/1/00

2/00

# Strongid® Paste

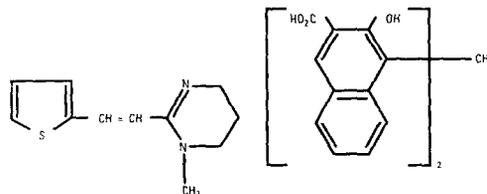
(pyrantel pamoate)

Equine Anthelmintic

## Read Entire Package Insert Carefully Before Using This Product

**DESCRIPTION:** Strongid Paste is a pale yellow to buff paste containing 43.9% w/w pyrantel pamoate in an inert vehicle. Each syringe contains 3.6 grams of pyrantel base in 23.6 grams (20 mL) paste. Each mL contains 180 mg pyrantel base as pyrantel pamoate.

**COMPOSITION:** 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.



**Chemical name:** (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)-vinyl]-pyrimidine 4,4'-methylenebis [3-hydroxy-2-naphtholate] (1:1)

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**Note:** Position screw-gauge over appropriate mark on plunger. Each mL contains 180 mg of pyrantel base as pyrantel pamoate.

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

**ADMINISTRATION:** After removing the cap, the paste should be deposited on the dorsum of the tongue. Introduce the nozzle end of the syringe at the corner of the mouth. Direct the syringe backwards and depress the plunger to deposit the paste onto the tongue. Given in this manner, it is unlikely that rejection of the paste will occur. Raising the horse's head sometimes assists in the swallowing process. When only part of the paste has been used, replace the cap on the syringe nozzle.

**EFFICACY:** Critical (worm count) studies in horses demonstrated that Strongid Paste 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%).

**WARNINGS:** Not for use in horses intended for food. Keep out of reach of children.

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

**RECOMMENDED STORAGE:** Store at controlled room temperature 15°-30°C (59°-86°F).

NADA #129-831, Approved by FDA

 **Animal Health**  
 Extol, PA 19341, USA  
 Div. of Pfizer Inc.  
 NY, NY 10017

75-7973-00  
 February 2000  
 Made in USA