FREEDOM OF INFORMATION (FOI) SUMMARY

Pyrantel Pamoate Paste
Equine Anthelmintic Paste
ANADA 200-342

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64503
1. GENERAL INFORMATION

ANADA: 200-342

Sponsor: Phoenix Scientific, Inc.
3915 South 48th 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 grants a waiver from the requirement of an in vitro 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 cuniculatum, 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. cuniculatum 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. cuniculatum, 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
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.

DOSAGE: Administer 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.

Body Weight | Volume | mg Pyrantel
---|---|---
< 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

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.

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.

NDC 50100-790-64

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

CUSTOMER PROOF • CHECK CAREFULLY!

Customer: PHOENIX SCIENTIFIC P.O. #: STEPHANIE

CYREL #: 28418 (LW) Date Sent: 5/10/00

LABEL: AM TECH PYRANTEL PAMOATE 20ML

SIZE: 3.5" X 3.0" VARNISH: YES PATTERN: NO FLOOD

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
AMO 200-363 Approved by FDA
Net Contents: 18.6g (15.9mL)

Amatechs

PYRANTEL PAMOATE PASTE is a yellow-green paste containing 10% pyrantel pamoate enclosed in units weighing 1.0 oz. Each unit contains 3.0 grams pyrantel paste in 1.8 grams base. Each tablet contains 120 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 phenylpiperazine. It is a white to off-white, odorless, crystalline, free-flowing, water-insoluble base and a colorless, odorless, crystalline, water-soluble acid. Pyrantel pamoate contains 34.7% base activity. The chemical structure and name are given below.

Chemical Name: (E)-1,4,9,9-tetrahydro-9-
methoxy-3-oxo-4-[[2,6-dichlorophenyl]amino]pyridine
(+)-(2S,3R,4R,5R)-2,3,5,6-tetrahydro-4-
methyl-4H-1,3-oxazin-4-one (CIPROFLOXACIN)

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 package has four weight mark intervals. Each weight mark indicates the recommended dose for 100 pounds of body weight.

DOSEAGE

NOTE: Position screw-gage over dispense mark on plunger. Each tablet contains 20 milligrams pyrantel base as pyrantel pamoate.

For maximum control of parasitemia, it is recommended that 200 mg of pyrantel be given monthly to treat the potential source of infection that the horse may have to the first, the horse should be treated every 6 months to control the infection.

ADMINISTRATION
After removing the cap, the paste should be dispensed on the tongue. The paste should be administered in a single dose. The paste should be absorbed in the stomach, where it is converted to the active form. If the paste is used, repeat the dose on the day of the paste.

WARNING! NOT FOR USE IN HORSES - KEEPIR OUT OF REACH OF CHILDREN

EQUINE ANTHELMINTIC
Approved for: Horses

INDICATIONS FOR USE
For the removal and control of intestinal infections of large nematodes (roundworms) and some larger nematodes (tapeworms) and some larger nematodes in horses and ponies.

STORE AT A CONTROLLED ROOM TEMPERATURE OF 20°C (68°F)

MANUFACTURED BY No. 5-0

CUSTOMER PROOF • CHECK CAREFULLY!

Customer: AM-TECH P.O. #: STEPHANIE

CYREL #: 28419 (ts) Date: 5/18/00

LABEL: pyrantel pamoate

UNWIND #: 

SIZE: 2.25 x 6.5

VARNISH: [ ] YES [ ]PATTERN [ ]FLOOD

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 ensure 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
FOR ORAL USE IN HORSES ONLY
Net Wt: 12 x 18.8 g (15.9 mL)
PYRANTEL PAMOATE PASTE
Equine Anthelmintic
FOR ORAL USE IN HORSES ONLY

NADA 050-046, Approved by FDA
Net Wt: 8 x 18.8 g (15.9 mL)

Store at controlled room temperature 20°-25°C (68°-77°F)
Contents of each unit may be up to 13.5% of body weight.

Net Wt: 8 x 18.8 g (15.9 mL)
Strongid® Paste
(pyrantel pamoate)
Equine Anthelmintic

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 2.6 grams of pyrantel base in 22.6 grams of paste.
Strongid® Paste
(pyrantel pamoate)
Equine Anthelmintic
Net Contents: 20 mL (23.6 g)
For animal use only
NADA #129-831, Approved by FDA

Active ingredient: Each 0.5-mL syringe contains 5 mg pyrantel pamoate.

Indications for Use: For the removal and control of mature infections of large strongyles (Strongylus vulgaris, S. equinus, S.wartii), small strongyles (Cyathostomum spp.), and large roundworms (Parascaris equorum) in horses and ponies.

Directions for Use: Administer as a single oral dose of 3 mg pyrantel pamoate base per lb of body weight. The syringe has 4 weight mark increments. Each weight mark indicates the recommended dose for 10 lb of body weight.

<table>
<thead>
<tr>
<th>Body Weight Range</th>
<th>1/4 syringe (5 mL)</th>
<th>1/2 syringe (10 mL)</th>
<th>1 syringe (20 mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 300 lb</td>
<td>900 mg</td>
<td>1800 mg</td>
<td>3600 mg</td>
</tr>
<tr>
<td>301–600 lb</td>
<td>1500 mg</td>
<td>3000 mg</td>
<td>6000 mg</td>
</tr>
<tr>
<td>601–900 lb</td>
<td>2100 mg</td>
<td>4200 mg</td>
<td>8400 mg</td>
</tr>
<tr>
<td>901–1200 lb</td>
<td>2700 mg</td>
<td>5400 mg</td>
<td>10800 mg</td>
</tr>
<tr>
<td>1201–1500 lb</td>
<td>3300 mg</td>
<td>6600 mg</td>
<td>13200 mg</td>
</tr>
<tr>
<td>&gt;1500 lb</td>
<td>4000 mg</td>
<td>8000 mg</td>
<td>16000 mg</td>
</tr>
</tbody>
</table>

Note: For heavily infested horses, a second dose may be required. 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 parasites.

Recommended Storage: Store at room temperature (55°–95°F/12°–35°C).

Refer to Package Insert for Complete Use Directions

Distributed by
Animal Health
7631 S. 1500 East, Salt Lake City, Utah 84107
U.S.A. 801-295-8521

Made in USA

1156
10/1/00

129-231 #5
(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-soluble crystalline salt of the tetrahydropyrimidine base and pamoic acid containing 34.7% base activity. The chemical structure and name are given below.

![Chemical structure of pyrantel pamoate](image)

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)

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 parasitemia.

DOSAGE AND TREATMENT: Strongid Paste is to be administered 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.

February 2000
**Dosage**

<table>
<thead>
<tr>
<th>Body Weight Range</th>
<th>Volume</th>
<th>mg Pyrantel Base</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 300 lb</td>
<td>1/4 syringe (5 mL)</td>
<td>900 mg</td>
</tr>
<tr>
<td>301–600 lb</td>
<td>1/2 syringe (10 mL)</td>
<td>1800 mg</td>
</tr>
<tr>
<td>601–900 lb</td>
<td>3/4 syringe (15 mL)</td>
<td>2700 mg</td>
</tr>
<tr>
<td>901–1200 lb</td>
<td>1 full syringe (20 mL)</td>
<td>3600 mg</td>
</tr>
</tbody>
</table>

**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 6 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

Distributed by **Pfizer Animal Health**

Exton, PA 19341, USA

Bar of Horse Inc.
NY, NY 10017

February 2000

Made in USA