

HFA 305

Date of Approval: _____

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-353

PRIMEX Equine

(50 mg of pyrantel base as pyrantel pamoate per mL)

Anthelmintic Suspension

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

Sponsored by:

**First Priority, Inc.
1585 Todd Farm Drive
Elgin, IL 60123-1146**

ANADA 200-353

FOIS 1

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-353
- b. Sponsor: First Priority, Inc.
1585 Todd Farm Drive
Elgin, IL 60123-1146

Drug Labeler Code: 058829
- c. Established Name: Pyrantel pamoate
- d. Proprietary Name: PRIMEX Equine
- e. Dosage Form: Suspension
- f. How Supplied: 32 fl. oz. (960 mL) bottle
- g. How Dispensed: Rx
- h. Amount of Active Ingredient: 50 milligrams of pyrantel base as pyrantel pamoate per mL.
- 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 PRIMEX Equine per 100 lb body weight).
- l. Pharmacological Category: Anthelmintic
- m. Indications: For the removal and control of mature large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pin worms (*Oxyuris equi*); large roundworms (*Parascaris equorum*) and small strongyles in horses and ponies.
- n. Pioneer Product: STRONGID T (pyrantel pamoate); NADA 91-739; Pfizer Inc.

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) 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).

Based on the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver from the requirements for an *in vivo* bioequivalence study for the generic product PRIMEX Equine (pyrantel pamoate). The generic product is administered as an oral suspension, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product STRONGID T (pyrantel pamoate), NADA 91-739, was approved on October 19, 1973.

3. HUMAN FOOD SAFETY:

This drug is indicated for use only in horses and ponies, which are non-food animals. Because 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.

Human food safety and human exposure warning statements are provided on the product label as follows: **“For Animal Use Only • Keep Out of Reach of Children.” “Not For Horses Or Ponies Intended For Food.”**

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that PRIMEX Equine, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Generic Labeling for ANADA 200-353:

PRIMEX Equine, 50 mg of pyrantel base as pyrantel pamoate per mL
1 – 32 fl oz (960 mL) container label with accompanying package insert.

ANADA 200-353

Pioneer Labeling for NADA 91-739:

Pfizer Inc.'s STRONGID T, 50 mg of pyrantel base as pyrantel pamoate per mL.
1 – Quart (946 mL) container label with accompanying package insert.

NDC# 58629-314-32



Primex™ Equine

Anthelmintic Suspension
(pyrantel pamoate)

Active Ingredient: 50 mg of Pyrantel
Base as Pyrantel Pamoate per mL

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.

DIRECTIONS FOR USE: Primex™ Equine may be administered by means of a stomach tube, dose syringe or by mixing into the feed. Administer 3 mg pyrantel base per pound of body weight (8 mL Primex™ Equine (pyrantel pamoate) per 100 lb body weight). It is recommended that severely debilitated animals not be treated with this preparation.

Stomach Tube - Measure the appropriate dosage of Primex™ Equine and mix in the desired quantity of water. Protect drench from direct sunlight and administer to the animal immediately following mixing. Do not attempt to store diluted suspension. Primex™ Equine is inactive against the common horse bot (*Gastrophilus spp.*). However, Primex™ Equine may be administered concurrently with carbon disulfide observing the usual precautions with carbon disulfide.

Dose Syringe - Draw the appropriate dosage of Primex™ Equine into a dose syringe and administer to the animal. Do not expose Primex™ Equine to direct sunlight.

Feed - Mix the appropriate dosage of Primex™ Equine in the normal grain ration. Fasting of animals prior to or following treatment is not required.

INGREDIENTS: 50 mg of pyrantel base as pyrantel pamoate per mL.

WARNING: NOT FOR HORSES OR PONIES INTENDED FOR FOOD.

READ ACCOMPANYING PROFESSIONAL INFORMATION.

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.

STORAGE: Store at controlled room temperature between 15°-30°C (59°-86°F). Keep container tightly closed when not in use.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.



For Animal Use Only • Keep Out of Reach of Children
Net Contents: 32 fl oz (960 mL)

LOT NO. Exp. Date
NO VARNISH

Iss. 07-03

Reorder No. OM100PC

ANADA 200-353, Approved by FDA

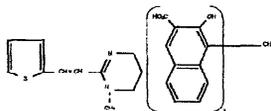
Primex™ Equine

Anthelmintic Suspension (pyrantel pamoate)

FOR ANIMAL USE ONLY

Primex™ Equine is a suspension of pyrantel pamoate in a palatable mint-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 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.

DIRECTIONS FOR USE: Primex™ Equine may be administered by means of a stomach tube, dose syringe or by mixing into the feed. Administer 3 mg pyrantel base per pound of body weight (6 mL Primex™ Equine (pyrantel pamoate) per 100 lb body weight). It is recommended that severely debilitated animals not be treated with this preparation. 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.

Stomach Tube - Measure the appropriate dosage of Primex™ Equine and mix in the desired quantity of water. Protect drench from direct sunlight and administer to the animal immediately following mixing. Do not attempt to store diluted suspension. Primex™ Equine is inactive against the common horse bot (*Gastrophilus* spp). However, Primex™ Equine may be administered concurrently with carbon disulfide observing the usual precautions with carbon disulfide.

Dose Syringe - Draw the appropriate dosage of Primex™ Equine into a dose syringe and administer to the animal. Do not expose Primex™ Equine to direct sunlight.

Feed - Mix the appropriate dosage of Primex™ Equine in the normal grain ration. Fasting of animals prior to or following treatment is not required.

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

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.

WARNING: Not for horses or ponies intended for food. Keep out of the reach of children.

SAFETY AND EFFICACY: Primex™ Equine is well tolerated by horses and ponies of all ages. Adverse drug response was not observed when dose rates up to 60 mg pyrantel base per lb of body weight were administered by stomach tube nor when 3 mg base per lb was given by intratracheal injection. The reproductive performance of pregnant mares and stud horses dosed with pyrantel pamoate suspension has not been affected. Critical (worm count) studies in horses demonstrated that pyrantel pamoate suspension 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%).

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PRESENTATION: 32 fl oz (960 mL).



Iss. 06-03



Manufactured By:
FIRST PRIORITY, INC.
Elgin, IL 60123-1146

ANADA 200-353.
Approved by FDA

FRONT

BACK

UNI-LABEL & TAG 1121 Pagni Drive, Elk Grove Village, IL 60007 • Phone (847) 956-8900 FAX (847) 956-8909

100% PROOF

Date of Origin: 6/13/02
Job No.: 02-3463
Customer: Priority One Control #: 161806
Part No.: LBPCOM100P NDC# 58829-314-32
Description: Insert Equine Anthelmintic Suspension
SIZE: 9.00" x 3.00"
Operator: JA
Date: 7/23/03



Black

PANTONE
348

PANTONE
466



Dieline

PROOF DOCUMENTATION

	DATE	DESCRIPTION OF REVISION REQUIRED
PROOF A	6/13/02	New art
PROOF B	6/20/02	Change to insert
PROOF C	7/3/02	Made changes per fax
PROOF D	1/9/03	Made changes per fax
PROOF E	1/10/03	Made changes per fax
PROOF F	2/26/03	Cust. changes
PROOF G	6/11/03	Type Changes
PROOF H	7/18/03	Customer supplied text changes
PROOF I	7/21/03	Removed Anthelmintic suspension

APPROVED BY _____



Strongid® T

(pyrantel pamoate)

Equine Anthelmintic Suspension

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

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Net Contents: 1 quart (946 mL)

NADA #91-739, Approved by FDA



Directions for Use: Strongid® T may be administered by means of a stomach tube, dose syringe or by mixing into the feed.

Caution: This product is a suspension and as such will separate; for more uniform resuspension and to achieve proper dosage, it is extremely important that the product be shaken and stirred thoroughly before every use.

Strongid® T may be administered by the appropriate dosage of Strongid® T and milk in the indicated quantity of water. Protect animals from direct sunlight and administer for the animal immediately following the dose. Do not store in a warm, humid environment. Strongid® T is inactive against the common horse bot (*Gasterophilus spp.*) although Strongid® T may be administered in conjunction with other deworming products observing the usual precautions and vaccination schedule.

Dose Syringe: Draw the appropriate dosage of Strongid® T into a dose syringe and administer to the animal. Do not expose Strongid® T to direct sunlight.

Feed: Mix the appropriate dosage of Strongid® T in the normal grain ration. Feeding of animals prior to or following treatment is not required.

Indications for Use: For the removal and control of mature infections of the respiratory tract (*Corynebacterium*, *S. pneumoniae*, *S. equorum*), the stomach (*Gastrophilus spp.*), large roundworms (*Parascaris equorum*), and small strongyles in horses and ponies.

Dosage: Administer 3 mg of pyrantel base per lb of body weight (10 mg Strongid® T per 100 lb of body weight). It is recommended that severely debilitated animals not be treated without proper hydration.

Warnings: Not for horses or ponies intended for food. Keep out of reach of children.

Rapid Assessment (Rapid) Insect Baiting Use
Recommended Storage: Store below 30°C (86°F). **DATE MADE**



Developed by
Pfizer Animal Health
Kenilworth, NJ, USA
Kenilworth, NJ, USA
NY, NY 10017



004 85 7372 00
MADE IN USA

Pioneer - Container Label

91-739 #17,

10-14-02



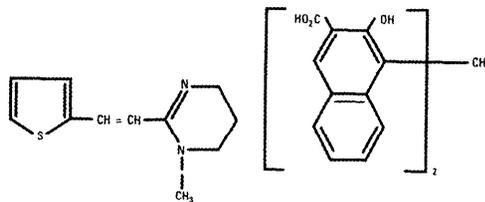
Strongid® T

(pyrantel pamoate)

Equine Anthelmintic Suspension

Strongid T is a suspension of pyrantel pamoate in a palatable caramel-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 lb of body weight (6 mL Strongid T per 100 lb of 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: Strongid T may be administered by means of a stomach tube, dose syringe or by mixing into the feed.

Stomach Tube: Measure the appropriate dosage of Strongid T and mix in the desired quantity of water. Protect drench from direct sunlight and administer to the animal immediately following mixing. Do not attempt to store diluted suspension.

Strongid T is inactive against the common horse bot (*Gastrophilus* spp.) However, Strongid T may be administered concurrently with carbon disulfide observing the usual precautions with carbon disulfide.

Dose Syringe: Draw the appropriate dosage of Strongid T into a dose syringe and administer to the animal. Do not expose Strongid T to direct sunlight.

Feed: Mix the appropriate dosage of Strongid T in the normal grain ration. Fasting of animals prior to or following treatment is not required.

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75-7972-01

Pioneer - Package Insect

Pfizer

CAUTION: THIS PRODUCT IS A SUSPENSION AND AS SUCH WILL SEPARATE. TO INSURE UNIFORM RESUSPENSION 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 Strongid T 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: Strongid T is well tolerated by horses and ponies of all ages. No adverse drug response was observed when dose rates up to 60 mg of pyrantel base per lb of body weight were administered by stomach tube nor when 3 mg base per lb was given by intratracheal injection. The reproductive performance of pregnant mares and stud horses dosed with Strongid T has not been affected.

▶ **WARNINGS:** Not for horses or ponies intended for food. Keep out of reach of children. ◀

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

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

NADA #91-739, Approved by FDA

TAKE TIME



OBSERVE LABEL
DIRECTIONS



Distributed by:

Animal Health

Exton, PA 19341, USA

Div. of Pfizer Inc

NY, NY 10017

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75-7972-01
Printed in USA