

SEP 26 2000

FREEDOM OF INFORMATION (FOI) SUMMARY

Continuex™ (pyrantel tartrate)

ANADA 200-282

Farnam Companies, inc.

301 W. Osborn Road

Phoenix, AZ 85013-3928

Date of Approval _____

ANADA 200-282

FOIS 1

Freedom of Information Summary

I. GENERAL INFORMATION

ANADA Number: 200-282

Sponsor: Farnam Companies, Inc.
301 W. Osborn Road
Phoenix, AZ 85013-3928

Generic Name: Pyrantel tartrate

Trade Name: Continuex™

Marketing Status: OTC

Species: Equine

II. Indications for Use

For the prevention of *Stongyls vulgaris* larval infections in horses.

For control of the following parasites in horses:

LARGE STRONGYLES (adults) *S. vulgaris*, *S. edentatus*, *Triodontophorus* spp.

SMALL STRONGYLES (adult and forth-stage larvae) *Cyathostomum* spp.

Cylicocyclus spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp.

PINWORMS (adult and fourth-stage larvae) *Oxyuris equi*

ASCARIDS (adule and fourth-stage larvae) *Parascaris equorum*

Pioneer Product: Strongid 48 (pyrantel tartrate), Pfizer, Inc. (NADA 140-819)

III. Dosage Form: Pyrantel tartrate is a Type A Medicated Article [concentration of 10.6% (48 grams per pound)] as pyrantel tartrate. To be used in formulating Type B medicated feeds (finished formulation) which are pelleted [concentration of 2.11% (9.6 grams per pound)].

Route of Administration

To be administered orally in the feed as either a top dress or mixed in the horses daily grain ration.

Recommended Dosage

Pyrantel tartrate is to be administered on a daily basis at the rate of 1.2 mg/lb (2.64 mg/kg) body weight daily. The duration of administration is for the period during which the animal is at risk of exposure to internal parasites.

IV. 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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will be required to include bioequivalence and residue studies. A tissue residue study will generally be required to accompany a clinical end-point, pharmacologic end-point, or blood level bioequivalence study that can not quantify the concentration of the drug in the blood through out the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalency study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalency Guideline, April 1996).

Based on the formulation characteristics of the generic product, Farnam Companies, Inc. was granted a waiver April 1, 1998, from conducting an *in vivo* bioequivalence study with pyrantel tartrate.

IV. HUMAN FOOD SAFETY

The drug is labeled: "Not for use in horses intended for food." Data on human food safety were not required for approval of this Abbreviated New Animal Drug Application.

V. 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 Continuex (pyrantel tartrate medicated feed) when used under its proposed conditions of use, is safe and effective for the labeled indications.

Attachment: Generic and pioneer labeling.

Type A

Type B

CONTINUEX PREMIX 10.6%

(pyrantel tartrate)

TYPE A MEDICATED ARTICLE EQUINE ANTHELMINTIC

Active Drug Ingredient: Pyrantel tartrate10.6% (48 grams per pound)

INDICATIONS FOR USE:

For the prevention of *Strongylus vulgaris* larval infestation in horses.

For control of the following parasites in horses:

LARGE STRONGYLES (adults) - *S. vulgaris*, *S. edentatus*

SMALL STRONGYLES (adults and fourth-stage larvae) - *Cyathostomum* spp.,

Cylicocycclus spp., *Cylicostephanus* spp., *Cylicodontophorus* spp.,

Poteriostomum spp., *Triodontophorus* spp.

PINWORMS (adults and fourth-stage larvae) - *Oxyuris equi*

ASCARIDS (adults and fourth-stage larvae) - *Parascaris equorum*

→ **WARNING: NOT FOR USE IN HORSES INTENDED FOR FOOD** ←

FOR USE IN THE MANUFACTURING OF EQUINE FEEDS ONLY

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respiratory and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed, wash before eating or leaving a work site; be alert to signs of allergic reactions - seek prompt medical attention if such reactions are suspected.

SEE BACK OF PACKAGE FOR FURTHER USE DIRECTIONS
STORE AT CONTROLLED ROOM TEMPERATURE 15-30°C (59-86°F)

ANADA 200-282 50 lb (22.6 kg)

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Farnam Companies
Phoenix, AZ 85013

typeA.doc

CONTINUEX PREMIX 10.6%

(pyrantel tartrate)

TYPE A MEDICATED ARTICLE EQUINE ANTHELMINTIC

MIXING AND USE DIRECTIONS

Continuex Premix 10.6% is to be administered on a continuous basis either as top-dress or mixed in the horse's daily grain ration at the rate of 1.2 mg/lb (2.64 mg/kg) body weight daily. The duration of administration is for the period during which the horse is at risk of exposure to internal parasites.

Foals may be treated at such time when consistent intake of grain mix is occurring. This is generally between two to three months of age.

Continuex Premix 10.6% may be used in mares at any stage of pregnancy or lactation. Stallion fertility is not affected by the use of Continuex Premix 10.6%

TYPICAL MIXING DIRECTIONS TO DELIVER 1.2 mg/lb (2.64 mg/kg)

LB OF MEDICATED GRAIN MIX PER 100 LB OF BODY WEIGHT	LB OF Continuex Premix 10.6%	LB OF NON-MEDICATED FEED	RESULTING CONCENTRATION G/TON
2.00	2.5	1997.5	120
1.50	3.3	1996.7	160
1.00	5.0	1995.0	240
0.50	10.0	1990.0	480
0.20	25.0	1975.0	1,200
LB OF MEDICATED TOP-DRESS PER 100 LB OF BODY WEIGHT			
0.04	125.0	1,875.0	6,000
0.025	200.0	1,800.0	9,600
0.02	250.0	1,750.0	12,000

→ WARNING: NOT FOR USE IN HORSES INTENDED FOR FOOD ←

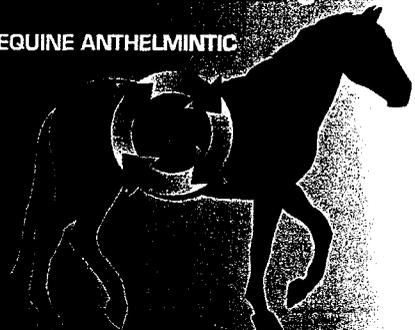
CAUTION: CONSULT YOUR VETERINARIAN BEFORE USING IN SEVERELY DEBILITATED ANIMALS AND FOR ASSISTANCE IN THE DIAGNOSIS, TREATMENT AND CONTROL OF PARASITISM. DO NOT MIX IN FEEDS CONTAINING BENTONITE.

		NEW
CONTINUEX™		
(pyrantel tartrate)		
For the prevention of <i>Strongylus vulgaris</i> larval infections in horses		
For Control of the following parasites in horses:		
LARGE STRONGYLES (adults) - <i>S. vulgaris</i> , <i>S. edentatus</i> , <i>Triodontophorus</i> spp.		
SMALL STRONGYLES (adults and fourth stage larvae) - <i>Cyathostomum</i> spp., <i>Cylicocycylus</i> spp., <i>Cylicodontophorus</i> spp., <i>Poteriostomum</i> spp.		
PINWORMS (adults and fourth stage larvae) - <i>Oxyuris equi</i>		
ASCARIDS (adults and fourth stage larvae) - <i>Parascaris equorum</i>		
ACTIVE DRUG INGREDIENT	INGREDIENTS	
Pyrantel tartrate2.11% (9.6 g/lb)	Dehydrated Alfalfa Meal, Wheat Middlings, Cane Molasses and Preserved with Propionic Acid.	
GUARANTEED ANALYSIS	ANADA 200-282	
Crude Protein, not less than11.5%		
Crude Fat, not less than1.5%		
Crude Fiber, not less than22.0%		
(SEE BACK PANEL FOR FURTHER USE DIRECTIONS)		
NET WEIGHT 3.75 LB (1.7 kg)		

DAILY DEWORMER

Medicated for Continuous Feeding

EQUINE ANTHELMINTIC



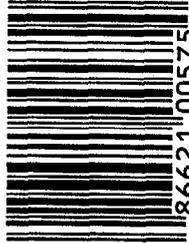


CONTINUEX™

(pyrantel tartrate)

MIXING AND FEEDING DIRECTIONS

Continuex™ (pyrantel tartrate) is to be administered on a continuous basis either as a top-dress or mixed in the horse's daily grain ration at the rate of 1.2 mg pyrantel tartrate per pound of body weight daily. To achieve this dose administer 0.5 oz. of Continuex per 250 lb. of body weight. (A Continuex measuring cup is enclosed.) Continuex should be administered for the entire period that the animal is at risk to internal parasites. Unprotected animals that have grazed may have already established *S. vulgaris* larval infection. Before administering Continuex, these animals should be treated with a therapeutic dose of a larvicidal product.



Foals may be administered Continuex as soon as consistent intake of grain mix is occurring. This is generally between two to three months of age. Continuex may be used in mares at any stage of pregnancy or lactation. Stallion fertility is not affected by the use of Continuex.

Store at controlled room temperature 15-30°C (59-86°F)

WARNING:
Do not use in horses
intended for food.

(SEE FRONT PANEL
FOR FURTHER
USE DIRECTIONS)

TOP-DRESS DIRECTIONS

LB BODY WEIGHT	OUNCES PER DAY OF CONTINUEX
250	0.5
500	1.0
750	1.5
1000	2.0
1250	2.5

(Measuring Cup Enclosed)

MEDICATED GRAIN MIX DIRECTIONS

LB OF MEDICATED GRAIN MIX PER 100 LB OF BODY WEIGHT	LB OF CONTINUEX	LB OF NON-MEDICATED FEED	CONCENTRATION GRAMS PER TON
2.0	12.5	1987.5	120
1.5	16.5	1983.5	160
1.0	25.0	1975	240
0.5	50.0	1950	480
0.2	125.0	1875	1200

CAUTION: Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment and control of parasitism. Do not mix in feeds containing bertonite.



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Phoenix, AZ 85013

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NEW

CONTINUEX™

(pyrantel tartrate)

DAILY DEWORMER

Medicated for Continuous Feeding

EQUINE ANTHELMINTIC



For the prevention of Strongylus vulgaris larval infections in horses

For Control of the following parasites in horses:

LARGE STRONGYLES (adults) - *S. vulgaris*, *S. edentatus*, *Triodontophorus* spp.

SMALL STRONGYLES (adults and fourth stage larvae) - *Cyathostomum* spp., *Cylicocycylus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp.

PINWORMS (adults and fourth stage larvae) - *Oxyuris equi*

ASCARIDS (adults and fourth stage larvae) - *Parascaris equorum*

ACTIVE DRUG INGREDIENT

Pyrantel tartrate.....2.11% (9.6 g/lb)

GUARANTEED ANALYSIS

Crude Protein, not less than.....11.5%

Crude Fat, not less than.....1.5%

Crude Fiber, not less than.....22.0%

INGREDIENTS

Dehydrated Alfalfa Meal, Wheat Middlings, Cane Molasses and Preserved with Propionic Acid.

ANADA 200-282

(SEE BACK PANEL FOR FURTHER USE DIRECTIONS)

NET WEIGHT 7.5 LB (3.44 kg)

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T12 Bucket



CONTINUEX™

(pyrantel tartrate)

MIXING AND FEEDING DIRECTIONS

Continuex™ (pyrantel tartrate) is to be administered on a continuous basis either as a top-dress or mixed in the horse's daily grain ration at the rate of 1.2 mg pyrantel tartrate per pound of body weight daily. To achieve this dose administer 0.5 oz. of Continuex per 250 lb. of body weight. (A Continuex measuring cup is enclosed.) Continuex should be administered for the entire period that the animal is at risk to internal parasites. Unprotected animals that have grazed may have already established *S. vulgaris* larval infection. Before administering Continuex, these animals should be treated with a therapeutic dose of a larvicidal product.

Foals may be administered Continuex as soon as consistent intake of grain mix is occurring. This is generally between two to three months of age.

Continuex may be used in mares at any stage of pregnancy or lactation. Stallion fertility is not affected by the use of Continuex.

TOP-DRESS DIRECTIONS

LB BODY WEIGHT	OUNCES PER DAY OF CONTINUEX
250	0.5
500	1.0
750	1.5
1000	2.0
1250	2.5

(Measuring Cup Enclosed)

MEDICATED GRAIN MIX DIRECTIONS

LB OF MEDICATED GRAIN MIX PER 100 LB OF BODY WEIGHT	LB OF CONTINUEX	LB OF NON-MEDICATED FEED	CONCENTRATION GRAMS PER TON
2.0	12.5	1987.5	120
1.5	16.5	1983.5	160
1.0	25.0	1975	240
0.5	50.0	1950	480
0.2	125.0	1875	1200

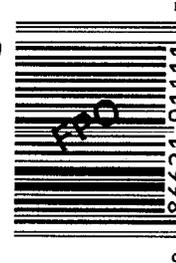
CAUTION: Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment and control of parasitism. Do not mix in feeds containing bentonite.

WARNING: Do not use in horses intended for food.

(SEE FRONT PANEL FOR FURTHER USE DIRECTIONS)

Store at controlled room temperature 15-30°C (59-86°F)

Continuex™ is the Farnam, Inc. trademark for pyrantel tartrate.



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NEW

FARNAM

CONTINUEX™

(pyrantel tartrate)

For the prevention of *Strongylus vulgaris* larval infections in horses

For Control of the following parasites in horses:

LARGE STRONGYLES (adults) - *S. vulgaris*, *S. edentatus*, *Triodontophorus* spp.

SMALL STRONGYLES (adults and fourth stage larvae) - *Cyathostomum* spp., *Cylicocycclus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp.

PINWORMS (adults and fourth stage larvae) - *Oxyuris equi*

ASCARIDS (adults and fourth stage larvae) - *Parascaris equorum*

ACTIVE DRUG INGREDIENT

Pyrantel tartrate2.11% (9.6 g/lb)

GUARANTEED ANALYSIS

Crude Protein, not less than11.5%

Crude Fat, not less than1.5%

Crude Fiber, not less than22.0%

INGREDIENTS

Dehydrated Alfalfa Meal, Wheat Middlings, Cane Molasses and Preserved with Propionic Acid.

ANADA 200-282

(SEE BACK PANEL FOR FURTHER USE DIRECTIONS)

NET WEIGHT 10 LB (4.54 kg)

DAILY DEWORMER

Medicated for Continuous Feeding

EQUINE ANTHELMINTIC





CONTINUEX™

(pyrantel tartrate)

MIXING AND FEEDING DIRECTIONS

Continuex™ (pyrantel tartrate) is to be administered on a continuous basis either as a top-dress or mixed in the horse's daily grain ration at the rate of 1.2 mg pyrantel tartrate per pound of body weight daily. To achieve this dose administer 0.5 oz. of Continuex per 250 lb. of body weight. (A Continuex measuring cup is enclosed.) Continuex should be administered for the entire period that the animal is at risk to internal parasites. Unprotected animals that have grazed may have already established *S. vulgaris* larval infection. Before administering Continuex, these animals should be treated with a therapeutic dose of a larvicidal product.

Foals may be administered Continuex as soon as consistent intake of grain mix is occurring. This is generally between two to three months of age.

Continuex may be used in mares at any stage of pregnancy or lactation. Stallion fertility is not affected by the use of Continuex.

Store at controlled room temperature 15-30°C (59-86°F)



WARNING:
Do not use in horses
intended for food.

(SEE FRONT PANEL
FOR FURTHER
USE DIRECTIONS)

TOP-DRESS DIRECTIONS

LB BODY WEIGHT	OUNCES PER DAY OF CONTINUEX
250	0.5
500	1.0
750	1.5
1000	2.0
1250	2.5

(Measuring Cup Enclosed)

MEDICATED GRAIN MIX DIRECTIONS

LB OF MEDICATED GRAIN MIX PER 100 LB OF BODY WEIGHT	LB OF CONTINUEX	LB OF NON-MEDICATED FEED	CONCENTRATION GRAMS PER TON
2.0	12.5	1987.5	120
1.5	16.5	1983.5	160
1.0	25.0	1975	240
0.5	50.0	1950	480
0.2	125.0	1875	1200

CAUTION: Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment and control of parasitism. Do not mix in feeds containing bentonite.



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Farnam Companies, Inc.
Phoenix, AZ 85013



NEW

CONTINUEX™

(pyrantel tartrate)

For the prevention of Strongylus vulgaris larval infections in horses

For Control of the following parasites in horses:

LARGE STRONGYLES (adults) - *S. vulgaris*, *S. edentatus*, *Triodontophorus* spp.

SMALL STRONGYLES (adults and fourth stage larvae) - *Cyathostomum* spp., *Cylicocycclus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp.

PINWORMS (adults and fourth stage larvae) - *Oxyuris equi*

ASCARIDS (adults and fourth stage larvae) - *Parascaris equorum*

ACTIVE DRUG INGREDIENT

Pyrantel tartrate.....2.11% (9.6 g/lb)

GUARANTEED ANALYSIS

Crude Protein, not less than.....11.5%

Crude Fat, not less than.....1.5%

Crude Fiber, not less than.....22.0%

INGREDIENTS

Dehydrated Alfalfa Meal, Wheat Middlings, Cane Molasses and Preserved with Propionic Acid.

ANADA 200-282

(SEE BACK PANEL FOR FURTHER USE DIRECTIONS)

NET WEIGHT 25 LB (11.34 kg)

DAILY DEWORMER

Medicated for Continuous Feeding

EQUINE ANTHELMINTIC



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Ropak 5 Gal. Bucket



CONTINUEX™

(pyrantel tartrate)

MIXING AND FEEDING DIRECTIONS

Continuex™ (pyrantel tartrate) is to be administered on a continuous basis either as a top-dress or mixed in the horse's daily grain ration at the rate of 1.2 mg pyrantel tartrate per pound of body weight daily. To achieve this dose administer 0.5 oz. of Continuex per 250 lb. of body weight. (A Continuex measuring cup is enclosed.) Continuex should be administered for the entire period that the animal is at risk to internal parasites. Unprotected animals that have grazed may have already established *S. vulgaris* larval infection. Before administering Continuex, these animals should be treated with a therapeutic dose of a larvicidal product.

Foals may be administered Continuex as soon as consistent intake of grain mix is occurring. This is generally between two to three months of age.

Continuex may be used in mares at any stage of pregnancy or lactation. Stallion fertility is not affected by the use of Continuex.

TOP-DRESS DIRECTIONS

LB BODY WEIGHT	OUNCES PER DAY OF CONTINUEX
250	0.5
500	1.0
750	1.5
1000	2.0
1250	2.5

(Measuring Cup Enclosed)

MEDICATED GRAIN MIX DIRECTIONS

LB OF MEDICATED GRAIN MIX PER 100 LB OF BODY WEIGHT	LB OF CONTINUEX	LB OF NON-MEDICATED FEED	CONCENTRATION GRAMS PER TON
2.0	12.5	1987.5	120
1.5	16.5	1983.5	160
1.0	25.0	1975	240
0.5	50.0	1950	480
0.2	125.0	1875	1200

CAUTION: Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment and control of parasitism. Do not mix in feeds containing bentonite.

WARNING:

Do not use in horses intended for food.

(SEE FRONT PANEL FOR FURTHER USE DIRECTIONS)

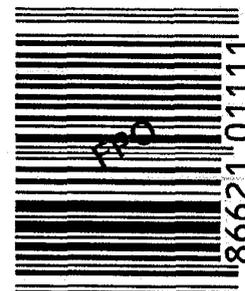
Store at controlled room temperature 15-30°C (59-86°F)

Continuex™ is the Farnam, Inc. trademark for pyrantel tartrate.



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86621 01111 3

(YELLOWISH GREEN BACKGROUND)



(WHITE BACKGROUND)

(PYRANTEL TARTRATE)
Strongid® 48



TYPE A MEDICATED ARTICLE

EQUINE ANTHELMINTIC

ACTIVE DRUG INGREDIENT: Pyrantel Tartrate...10.6% (48 grams per pound)

ADJUVANTS: Roughage Products, Calcium Carbonate, Sodium
Aluminosilicate and Mineral Oil.

INDICATIONS FOR USE:

For the prevention of *Strongylus vulgaris* larval infections in horses.

For control of the following parasites in horses:

LARGE STRONGYLES (adults)—*S. vulgaris*, *S. edentatus*, *Triodontophorus* spp.

SMALL STRONGYLES (adults and fourth-stage larvae)—*Cyathostomum*

spp., *Cylicocycclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp.,

Potestostomum spp.

PINWORMS (adults and fourth-stage larvae)—*Oxyuris equi*

ASCARIDS (adults and fourth-stage larvae)—*Parascaris equorum*

◆ **WARNING: NOT FOR USE IN HORSES INTENDED FOR FOOD.** ◆

FOR USE IN THE MANUFACTURING OF EQUINE FEEDS ONLY.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard if a source of bacterial contamination to certain individuals who are exposed to them. Human exposure should therefore be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: Skin contact or ingestion and protective clothing should be worn. Skin-irritating equipment and adequate ventilation should be utilized. Personal hygiene should be observed. Wash hands carefully or having a work day. Be sure to wear eye protection. Wash personal medical personnel's hands frequently and thoroughly.

SEE BACK OF PACKAGE FOR FURTHER USE DIRECTIONS
STORE IN DRY COOL PLACE

NET WEIGHT 50 LB

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

Print No. 3.549.624

Strongid® 48
(PYRANTEL TARTRATE)

(WHITE BACKGROUND)

(GUSSET)

(YELLOWISH GREEN BACKGROUND)

pfizer

(WHITE BACKGROUND)

pfizer

(PYRANTEL TARTRATE)

Strongid® 48

TYPE A MEDICATED ARTICLE

EQUINE ANTHELMINTIC

MIXING AND USE DIRECTIONS

Strongid is to be administered on a continuous basis either as a top-dress or mixed in the horse's daily grain ration at the rate of 1.2 mg/lb (2.64 mg/kg) body weight daily. The duration of administration is for the period during which the horse is at risk of exposure to internal parasites.

Foals may be treated at such time when consistent intake of grain mix is occurring. This is generally between two to three months of age.

Strongid may be used in mares at any stage of pregnancy or lactation. Stallion fertility is not affected by the use of Strongid.

TYPICAL MIXING DIRECTIONS TO DELIVER 1.2 mg/lb (2.64 mg/kg)

lb of medicated grain mix per 100 lb of body weight	lb of STRONGID 48	lb of non-medicated feed	Resulting Concentration g/ton
2.00	2.5	1997.5	120
1.50	3.3	1996.7	180
1.00	5.0	1995.0	240
0.50	10.0	1990.0	480
0.20	25.0	1975.0	1,200
lb of medicated top-dress per 100 lb of body weight			
0.04	125.0	1,875.0	6,000
0.025	200.0	1,800.0	9,600
0.02	250.0	1,750.0	12,000

(WHITE BACKGROUND)

Strongid® 48

(PYRANTEL TARTRATE)

(GUSSET)

⚠ **WARNING: NOT FOR USE IN HORSES INTENDED FOR FOOD.** ⚠

CAUTION: CONSULT YOUR VETERINARIAN BEFORE USING IN SEVERELY DEBILITATED ANIMALS AND FOR ASSISTANCE IN THE DIAGNOSIS, TREATMENT AND CONTROL OF PARASITISM. DO NOT MIX IN FEEDS CONTAINING BENTONITE.

