

HFA 305

Date of Approval: AUG 20

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-352

PRIMEX Canine-2X and PRIMEX Canine (pyrantel pamoate)

Anthelmintic Suspension

For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. To prevent reinfestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

Sponsored by:

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

2011 08 25 1:00

F015

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-352
- b. Sponsor: First Priority, Inc.
1585 Todd Farm Drive
Elgin, IL 60123-1146

Drug Labeler Code: 058829
- c. Established Name: Pyrantel pamoate
- d. Proprietary Names: PRIMEX Canine-2X and PRIMEX Canine
- e. Dosage Form: Suspension
- f. How Supplied: PRIMEX Canine-2X: 60 mL and 473 mL containers
PRIMEX Canine: 60 mL containers
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: PRIMEX Canine-2X: 4.54 milligrams of pyrantel base as pyrantel pamoate per mL.
PRIMEX Canine: 2.27 milligrams of pyrantel base as pyrantel pamoate per mL.
- i. Route of Administration: Oral
- j. Species/Class: Dogs and puppies
- k. Recommended Dosage: PRIMEX Canine-2X: Administer 1 full teaspoon (5 mL) for each 10 lb of body weight.
PRIMEX Canine: Administer 1 full teaspoon (5 mL) for each 5 lb of body weight.
- l. Pharmacological Category: Anthelmintic
- m. Indications: For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. To prevent reinfestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

- n. Pioneer Product: NEMEX-2 and RFD (pyrantel pamoate); NADA 100-237; 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 on July 3, 2001, from the requirement for an *in vivo* bioequivalence study for the generic products PRIMEX Canine-2X and PRIMEX Canine (pyrantel pamoate). The generic products are administered as an oral suspension, contain the same active ingredient in the same concentration and dosage form as the pioneer products, and contain no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer products NEMEX-2 and RFD (pyrantel pamoate), manufactured by Pfizer, Inc. (NADA 100-237), were approved on June 3, 1977.

3. HUMAN FOOD SAFETY:

This drug is intended for use in dogs and puppies, 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 warnings are provided on the product label as follows: **“For Animal Use Only • Keep Out of Reach of Children.”**

4. 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 PRIMEX Canine-2X and PRIMEX Canine, when used under their proposed conditions of use, are safe and effective when used for their labeled indications.

5. ATTACHMENTS:

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

Generic Labeling for ANADA 200-352:

PRIMEX Canine-2X (pyrantel pamoate), 4.54 mg/mL

1 – 60 mL and 1 – 473 mL container labels with accompanying insert

1 – 60 mL box label

PRIMEX Canine (pyrantel pamoate), 2.27 mg/mL.

1 – 60 mL container label with accompanying insert

1 – 60 mL box label

Pioneer Labeling for NADA 100-237:

Pfizer Inc.'s NEMEX-2 (pyrantel pamoate), 4.54 mg/mL

1 – 60 mL and 1 – 473 mL container labels with accompanying insert

1 – 60 mL box label

Pfizer's RFD (pyrantel pamoate), 2.27 mg/mL

1 – 60 mL container label with accompanying insert

1 – 60 mL box label

NDC# 58829-315-02

INDICATIONS: For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal exam. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Primex™ Canine-2X may also be used to prevent reinestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

DIRECTIONS FOR USE: Administer 1 full teaspoon (5 mL) for each 10 lb of body weight. To assure proper dosage, weigh animal prior to treatment. It is not necessary to withhold food prior to or after treatment. Dogs usually find this dewormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2-4 weeks after first treatment. If your dog looks or acts sick, consult your veterinarian before treatment. For maximum control and prevention of reinestation, it is recommended that puppies be treated at 2, 3, 4, 6, 8 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *Toxocara canis* reinestation.

Iss. 07-03

Priority Care



Primex™ Canine-2X

Anthelmintic Suspension
(pyrantel pamoate)

For Animal Use Only • Keep Out of Reach of Children

Net Contents: 2 fl oz (60 mL)

ANADA 200-352, Approved by FDA

ACTIVE INGREDIENT: 4.54 mg of pyrantel base as pyrantel pamoate per mL.

IMPORTANT: SHAKE WELL BEFORE USE.

REFER TO PACKAGE INSERT FOR COMPLETE DIRECTIONS

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

TAKE TIME



OBSERVE LABEL DIRECTIONS

Lot No.

Exp. Date

NO VARNISH

Header No. OM101PC



6230831502 X

@200%

NDC# 59829-315-16

Priority Care 

INDICATIONS: For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal exam. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Primex™ Canine-2X may also be used to prevent reinestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

DIRECTIONS FOR USE: Administer 1 full teaspoon (5 mL) for each 10 lb of body weight. To assure proper dosage, weigh animal prior to treatment. It is not necessary to withhold food prior to or after treatment. Dogs usually find this dewormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2-4 weeks after first treatment. If your dog looks or acts sick, consult your veterinarian before treatment. For maximum control and prevention of reinestation, it is recommended that puppies be treated at 2, 3, 4, 6, 8 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *Toxocara canis* reinestation.

Primex™ Canine-2X

Anthelmintic Suspension
(pyrantel pamoate)

ACTIVE INGREDIENT: 4.54 mg of pyrantel base as pyrantel pamoate per mL

IMPORTANT: SHAKE WELL BEFORE USE.

REFER TO PACKAGE INSERT FOR COMPLETE DIRECTIONS

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



Lot No. Exp. Date
VARNISH

 **VETERINARY LABEL**
100-07-03

For Animal Use Only • Keep Out of Reach of Children

Net Contents: 16 fl oz (473 mL)

Reorder No. OM102PC

ANADA 200-352, Approved by FDA

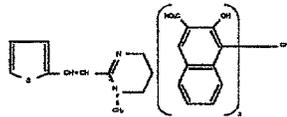
Primex™ Canine-2X

Anthelmintic Suspension
(pyrantel pamoate)

FOR ANIMAL USE ONLY

Primex™ Canine-2X is a suspension of pyrantel pamoate in a palatable butterscotch-flavored vehicle. Each mL contains 4.54 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 of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal exam. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Primex™ Canine-2X may also be used to prevent reinfestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

DIRECTIONS FOR USE: Administer 1 full teaspoon (5 mL) for each 10 lb of body weight. To assure proper dosage, weigh animal prior to treatment. It is not necessary to withhold food prior to or after treatment. Dogs usually find this dewormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2 to 4 weeks after first treatment. If your dog looks or acts sick, consult your veterinarian before treatment. For maximum control and prevention of reinfestation, it is recommended that puppies be treated at 2, 3, 4, 6, 8 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *Toxocara canis* reinfestation.

FRONT

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 THOROUGHLY BEFORE EVERY USE.

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

SAFETY AND EFFICACY: Critical (worm count) studies in dogs demonstrated that Primex™ Canine-2X at the recommended dosage is highly efficacious against *T. leonina* (99%), *T. canis* (85%), *A. caninum* (97%), and *U. stenocephala* (94%).

One of the most outstanding and significant features of Primex™ Canine-2X is its wide margin of therapeutic safety in dogs. The acute oral LD₅₀ of pyrantel pamoate administered in gelatin capsules to female and male dogs is greater than 314 mg base per lb of body weight, which indicates a therapeutic index in excess of 138 times the recommended dosage. In subacute and chronic studies, no significant morphological abnormalities could be attributed to pyrantel pamoate when administered to dogs at daily dose rates up to 94 mg base per lb of body weight (40x) for periods of 19, 30, and 90 days. Clinical studies conducted in a wide variety of geographic locations using more than 40 different breeds of dogs showed no drug-induced toxic effects. Included in these studies were nursing pups, weaned pups, adults, pregnant bitches, and males at stud. Additional data have demonstrated the safe use of pyrantel pamoate in dogs having heartworm infestations and/or receiving medication for heartworms, dogs exposed to organophosphate flea collars or flea/tick dip treatments, and dogs undergoing concurrent treatment or medication at the time of worming such as immunization and antibacterial treatment.

PRESENTATION: 2 fl oz (60 mL), 16 fl oz (473 mL) bottles.

KEEP OUT OF REACH OF CHILDREN



Iss. 07-03



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

ANADA 200-952,
Approved by FDA

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: 5/22/02
Job No.: 02-3465
Customer: Priority One Control #: 161808
Part No.: LBPCOM101P NDC# 58829-315-16
Description: Primex-2 INSERT
SIZE: 10.50" x 3.00"
Operator: JA
Date: 7/23/03

PROOF DOCUMENTATION

	DATE	DESCRIPTION OF REVISION REQUIRED
PROOF A	5/22/02	New art
PROOF B	6/4/02	Added more copy that was smaller ever, changed front and base to match other labels
PROOF C	6/11/02	Change layout
PROOF D	6/20/02	This will be an INSERT instead of an expandable label.
PROOF E	7/3/02	Make changes per fax
PROOF F	1/9/03	Made changes per fax
PROOF G	1/10/03	Made changes per fax
PROOF H	2/26/03	Customer changes

American Eagle Pkg.
 AE Pharma Bottle
 5/9/2003

DRAFT
 For Comp Only

NANDA 200-352, Approved by FDA

Canine Anthelmintic Suspension
 (pyrantel pamoate)

Primex™
Canine-2X

Priority Care
 (pyrantel pamoate)

Canine Anthelmintic Suspension
 (pyrantel pamoate)

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

For Animal Use Only -
 Keep Out of Reach of Children

ANADA 200-352
 Approved by FDA



Net Contents: 2 fl oz (60 mL)

INDICATIONS: For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal exam. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Primex™ Canine-2X may also be used to prevent reinfestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

ACTIVE INGREDIENT: 4.54 mg of pyrantel base as pyrantel pamoate per mL

188 07-03

SEE THE  **REVERSE LABEL** FOR DIRECTIONS

3-62306-31502-x

NANDA 200-352, Approved by FDA

Canine Anthelmintic Suspension
 (pyrantel pamoate)

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

For Animal Use Only -
 Keep Out of Reach of Children

ANADA 200-352
 Approved by FDA



Net Contents: 2 fl oz (60 mL)

DIRECTIONS FOR USE: Administer 1 full teaspoon (5 mL) for each 10 lb of body weight. To assure proper dosage, weigh animal prior to treatment. It is not necessary to withhold food prior to or after treatment. Dogs usually find this dewormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2-4 weeks after first treatment. If your dog looks or acts sick, consult your veterinarian before treatment. For maximum control and prevention of reinfestation, it is recommended that puppies be treated at 2, 3, 4, 6, 9 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *Toxocara canis* reinfestation.

IMPORTANT: SHAKE WELL BEFORE USE.

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

REFER TO PACKAGE INSERT FOR COMPLETE DIRECTIONS.

Lot No. Exp. Date

NO VARNISH

Line indicates minimum bleed

NDC# 58829-317-02

Priority Care

Primex™ Canine

Liquid Wormer for Puppies & Dogs
(pyrantel pamoate)

INDICATIONS: For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal exam. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Primex™ Canine may also be used to prevent reinestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

DIRECTIONS FOR USE: Administer 1 full teaspoon (5 mL) for each 5 lb of body weight. To assure proper dosage, weigh animal prior to treatment. It is not necessary to withhold food prior to or after treatment. Dogs usually find this dewormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2-4 weeks after first treatment. If your dog looks or acts sick, consult your veterinarian before treatment. For maximum control and prevention of reinestation, it is recommended that puppies be treated at 2, 3, 4, 6, 8 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *Toxocara canis* reinestation.

Iss. 07-09

ACTIVE INGREDIENT: 227 mg of pyrantel base as pyrantel pamoate per mL

IMPORTANT: SHAKE WELL BEFORE USE.

REFER TO PACKAGE INSERT FOR COMPLETE DIRECTIONS

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



TIME

LOT No.

Exp. Date

NO VARNISH

Reorder No. CMT103FC

POSITION ONLY
62330831702

For Animal Use Only • Keep Out of Reach of Children

Net Contents: 2 fl.oz (60 mL)

ANADA 200-352, Approved by FDA

@200%

Primex™ Canine

Liquid Wormer for Puppies & Dogs
Parasiticide-Oral
 (pyrantel pamoate)

Active Ingredient(s): 2.27mg of pyrantel base as pyrantel pamoate per mL.

INDICATIONS: For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal exam. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Primex™ Canine may also be used to prevent reinfestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

DIRECTIONS FOR USE: Administer 1 full teaspoon (5 mL) for each 5 lb of body weight. To assure proper dosage, weigh animal prior to treatment. It is not necessary to withhold food prior to or after treatment. Dogs usually find this dewormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under

conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2-4 weeks after first treatment. If your dog looks or acts sick, consult your veterinarian before treatment. For maximum control and prevention of reinfestation, it is recommended that puppies be treated at 2, 3, 4, 6, 8 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *Toxocara canis* reinfestation.

PRECAUTION: Shake well before use.

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

CAUTION: Keep out of reach of children

PRESENTATION: 2 fl oz (60 mL) bottles.



Iss. 06-03



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

ANADA 200-352,
 Approved by FDA

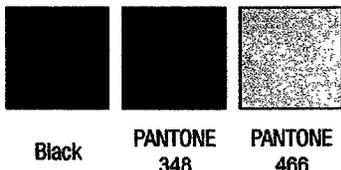
FRONT

BACK

UNI-LABEL & TAG 1121 Pagni Drive, Elk Grove Village, IL 60007 • Phone (847) 956-8900 FAX (847) 956-9

100% PROOF

Date of Origin: 5/22/02
 Job No.: 02-3478
 Customer: Priority One Control #: 161824
 Part No.: NDC# 58829-317-02
 Description: Primex-3 INSERT
SIZE: 5.25" x 3.00"
 Operator: JA
 Date: 7/21/03



Black

PANTONE
348

PANTONE
466

Dieline

PROOF DOCUMENTATION

	DATE	DESCRIPTION OF REVISION RE
PROOF A	5/22/02	New art
PROOF B	6/4/02	Added more copy that was emailed over, changed front and ba
PROOF C	6/11/02	Change layout
PROOF D	6/19/02	This will be an INSERT instead of an expa
PROOF E	7/3/02	Corrections per fax
PROOF F	1/8/03	Add "Iss. 01-03" and ANADA# 200-352
PROOF G	1/10/03	Change "ISS." to "Iss."
PROOF H	1/14/02	Made correction per fax
PROOF I	2/26/03	Customer Changes
PROOF J	5/20/03	Lengthened Green Lines
PROOF J	6/11/03	type corrections.
PROOF K	6/12/03	type corrections.

American Eagle Pkg.
 AE Pharma Bottle
 5/9/2003

DRAFT
 For Comp Only

Priority Care
Primex™ Canine
 (pyrantel pamoate)
Liquid Wormer
 for Puppies & Dogs

For Animal Use Only -
 Keep Out of Reach of Children
 ANADA 200-352,
 Approved by FDA

INDICATIONS: For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal exam. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Primex™ Canine may also be used to prevent reinfection of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

ACTIVE INGREDIENT: 2.27 mg of pyrantel base as pyrantel pamoate per mL

Net Contents: 2 fl oz (60 mL)

3-62306-31702-x

Priority Care
Primex™ Canine
 (pyrantel pamoate)
Liquid Wormer
 for Puppies & Dogs

For Animal Use Only -
 Keep Out of Reach of Children
 ANADA 200-352,
 Approved by FDA

DIRECTIONS FOR USE: Administer 1 full teaspoon (5 mL) for each 5 lb of body weight. To assure proper dosage, weigh animal prior to treatment. It is not necessary to withhold food prior to or after treatment. Dogs usually find this dewormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2-4 weeks after first treatment. If your dog looks or acts sick, consult your veterinarian before treatment. For maximum control and prevention of reinfection, it is recommended that puppies be treated at 2, 3, 4, 6, 8 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *Toxocara canis* reinfection.

IMPORTANT: SHAKE WELL BEFORE USE.

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

REFER TO PACKAGE INSERT FOR COMPLETE DIRECTIONS.

Lot No. Exp. Date

NO VARNISH

Line indicates minimum bleed

Bottle Label

INDICATIONS FOR USE:

To prevent reinfestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal examination. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Refer to package insert for complete directions.



WARNING
KEEP OUT OF REACH
OF CHILDREN

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



05-3227-30-4
12232-05-1

MADE IN CANADA

Distributed by
Animal Health
Pfizer Inc., Lee's Summit, MO 64081

4505

Nemex™ -2
(pyrantel pamoate)

**Canine Anthelmintic
Suspension**

Active Ingredient
4.54 mg of pyrantel base
as pyrantel pamoate per mL

FOR ANIMAL USE ONLY

NADA 100-237, Approved by FDA

Net Contents:
16 fl oz (473 mL)

pfizer

DIRECTIONS FOR USE:

For maximum control and prevention of reinfestation, it is recommended that puppies be treated at 2, 3, 4, 6, 8 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *T. Canis* reinfestation. Administer one full teaspoonful (5 mL) for each 10 lb of body weight.

i For the removal of large roundworms (ascarids) and hookworms. Administer one full teaspoonful (5 mL) for each 10 lb of body weight. It is not necessary to withhold food prior to or after treatment. If medication is to be dispensed client can be advised that dogs usually find this wormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2 to 4 weeks after first treatment.

**IMPORTANT: SHAKE
WELL BEFORE USE.**

LOT C94990
EXP 01/04

Bottle Label

DIRECTIONS FOR USE: Administer 1 teaspoon (5 mL) for each 10 lb of body weight. It is not necessary to withhold food prior to or after treatment. Dogs usually find this dewormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2-4 weeks after treatment.

For maximum control and prevention of reinfestation, it is recommended that puppies be treated at 2, 3, 4, 6, 8, and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *T. canis* reinfestation.



IMPORTANT: SHAKE WELL BEFORE USE

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

REFER TO PACKAGE INSERT FOR COMPLETE DIRECTIONS



KEEP OUT OF REACH OF CHILDREN

NEMEX™-2 (pyrantel pamoate)

**CANINE ANTHELMINTIC
SUSPENSION**

Active Ingredient: 4.54 mg
Of pyrantel base as pyrantel
pamoate per mL

**FOR ANIMAL
USE ONLY**

2 FL OZ (60 mL)

NADA #100-237, Approved by FDA

INDICATIONS FOR USE: For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal exam. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.



Nemex-2 suspension may also be used to prevent reinfestation of *T. canis* in puppies and adult dogs and in lactating bitches after whelping.



Distributed by:
Pfizer Animal Health
Exton, PA 19341, USA
Division of Pfizer Inc.
NY, NY 10017

Made in Canada
05-3192-30-8
12231-05-4

LOT CB4835
EXP 10/02

00010

Package Insert

Front

NEMEX™ -2

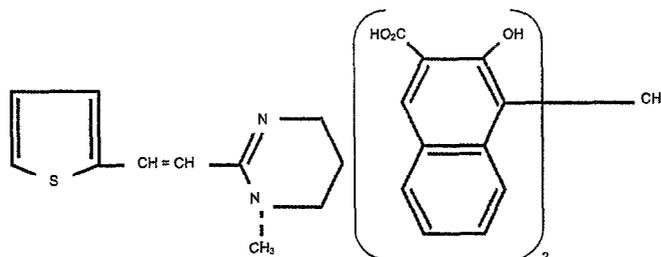
(pyrantel pamoate)

ANINE ANTHELMINTIC SUSPENSION

FOR ANIMAL USE ONLY

Nemex-2 is a suspension of pyrantel pamoate in a palatable caramel-flavored vehicle. Each mL contains 4.54 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: Nemex-2 suspension is a highly palatable formulation intended as a single treatment for the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal exam. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Nemex-2 suspension may also be used to prevent reinfestation of *T. canis* in puppies and adult dogs and in lactating bitches after whelping.

DIRECTIONS FOR USE: Administer 1 teaspoon (5 mL) for each 10 lb of body weight. It is not necessary to withhold food prior to or after treatment. Dogs usually find this dewormer very palatable and will lick the dose from the

Back

owl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2-4 weeks after treatment.

For maximum control and prevention of reinfestation, it is recommended that puppies be treated at 2, 3, 4, 6, 8, and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *T. canis* reinfestation.

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 THOROUGHLY BEFORE EVERY USE.

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

SAFETY AND EFFICACY: Critical (worm count) studies in dogs demonstrated that Nemex-2 at the recommended dosage is highly efficacious against *T. leonina* (99%), *T. canis* (85%), *A. caninum* (97%), and *U. stenocephala* (94%).

One of the most outstanding and significant features of Nemex-2 is its wide margin of therapeutic safety in dogs. The acute oral LD₅₀ of pyrantel pamoate administered in gelatin capsules to female and male dogs is greater than 314 mg base per lb of body weight, which indicates a therapeutic index in excess of 138 times the recommended dosage. In subacute and chronic studies, no significant morphological abnormalities could be attributed to Nemex-2 when administered to dogs at daily dose rates up to 94 mg base per lb of body weight (40x) for periods of 19, 30, and 90 days. Clinical studies conducted in a wide variety of geographic locations using more than 40 different breeds of dogs showed no drug-induced toxic effects. Included in these studies were nursing pups, weaned pups, adults, pregnant bitches, and males at stud. Additional data have demonstrated the safe use of Nemex-2 in dogs having heartworm infestations and/or receiving medication for heartworms, dogs exposed to organophosphate flea collars or flea/tick dip treatments, and dogs undergoing concurrent treatment or medication at the time of worming such as immunization and antibacterial treatment.

KEEP OUT OF REACH OF CHILDREN

NADA# 100-237, Approved by FDA



Distributed by:
Pfizer Animal Health
Exton, PA 19341, USA
Division of Pfizer Inc
NY, NY 10017

65-3192-30-6
12231-11-3
February 1997
Printed in Canada

00027

Box Label

NEMEX™-2
 (pyrantel pamoate)
 CANINE ANTHELMINTIC
 SUSPENSION

Box Top

INDICATIONS FOR USE: For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal exam. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Nemex-2 suspension may also be used to prevent reinfection of *T. Canis* in puppies and adult dogs and in lactating bitches after whelping.

KEEP OUT OF REACH OF CHILDREN



UPC BAR CODE
 0-87219-04507-7

Left Panel

NEMEX™-2
 (pyrantel pamoate)
 CANINE ANTHELMINTIC
 SUSPENSION

Active ingredient: 4.54 mg
 Of pyrantel base as pyrantel
 pamoate per mL

**FOR ANIMAL
 USE ONLY**

2 FL OZ (60 mL)

NADA #100-237, Approved by FDA

Back Panel

DIRECTIONS FOR USE: Administer 1 teaspoon (5 mL) for each 10 lb of body weight. It is not necessary to withhold food prior to or after treatment. Dogs usually find this dewormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2-4 weeks after treatment.

For maximum control and prevention of reinfection, it is recommended that puppies be treated at 2, 3, 4, 6, 8 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *T. canis* reinfection.

IMPORTANT: SHAKE WELL BEFORE USE

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

REFER TO PACKAGE INSERT FOR COMPLETE DIRECTIONS

Distributed by:
 Pfizer Animal Health
 Exton, PA 19341, USA
 Division of Pfizer Inc
 NY, NY 10017
 Made in Canada
 10-3192-30-9
 12231-14-4

Right Panel

C84835
 10/02

Box Bottom

NEMEX™-2
 (pyrantel pamoate)
 CANINE ANTHELMINTIC
 SUSPENSION

Active ingredient: 4.54 mg
 Of pyrantel base as pyrantel
 pamoate per mL

**FOR ANIMAL
 USE ONLY**

2 FL OZ (60 mL)

NADA #100-237, Approved by FDA

Front Panel

92000

PFIZER INC.
ANIMAL HEALTH GROUP
235 E. 42ND ST.
NEW YORK
NY 10017
USA

Telephone: 800-877-6250
Fax: 610-363-3280
General: 800-877-6250 or 610-363-3100
Customer Service (Orders): 800-733-5500
Technical Services (USA): 800-366-5288
Technical Services (Canada): 800-461-0917
Website: www.pfizer.com/ah

The following information is from the most recent U.S.A. product label/insert supplied to us by the Manufacturer/Distributor.

RFD® LIQUID WORMER

Pfizer Animal Health

Parasiticide-Oral
(pyrantel pamoate)

NADA No.: 100-237

Active Ingredient(s): 2.27 mg of pyrantel base as pyrantel pamoate per mL.

Indications: For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies. The presence of these parasites should be confirmed by laboratory fecal exam. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

RFD® Liquid Wormer may also be used to prevent reinfestation of *T. canis* in puppies and adult dogs and in lactating bitches after whelping.

Directions for Use: Administer 1 teaspoon (5 mL) for each 5 lb of body weight. To assure proper dosage, weigh animal prior to treatment. It is not necessary to withhold food prior to treatment. Dogs usually find this dewormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2-4 weeks after first treatment. If your dog looks or acts sick, consult your veterinarian before treatment.

For maximum control and prevention of reinfestation, it is recommended that puppies be treated at 2, 3, 4, 6, 8 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *T. canis* reinfestation.

Precaution(s): Recommended Storage: Store below 30°C (86°F).

Shake well before use.

Caution(s): Keep out of reach of children.

Presentation: 2 fl oz (60 mL) bottle.

85-7985-00

Disclaimer: Every effort has been made to ensure the accuracy of the information published. However, it remains the responsibility of the readers to familiarize themselves with the product information contained on the product label or package insert. Compendium Code No.: 36901850

Bottle Label

Easy to administer.

INDICATIONS FOR USE

To prevent reinfestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping. For the removal of large roundworms (ascarids), *Toxocara canis* and *Toxascaris leonina* and hookworms, *Ancylostoma caninum* and *Uncinaria stenocephala* in dogs. The presence of these parasites should be confirmed by laboratory fecal examination. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

ACTIVE INGREDIENT

2.27 mg of pyrantel base as pyrantel pamoate per mL
SHAKE WELL BEFORE USE

RECOMMENDED STORAGE

STORE BELOW 86°F (30°C)



WARNING: KEEP OUT OF REACH OF CHILDREN



05-4342-30-5

Distributed by
Animal Health
Pfizer Inc, Lee's Summit, MO 64081

MADE IN CANADA

4547

RFD®

(pyrantel pamoate)

**LIQUID
WORMER**

FOR PUPPIES AND DOGS
NADA #100-237, APPROVED BY FDA

Net Contents: 2 FL OZ (60 mL)

pfizer

DIRECTIONS FOR USE

For maximum control and prevention of reinfestation, it is recommended that puppies be treated at 2, 3, 4, 6, 8, and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent *T. Canis* reinfestation. Administer one full teaspoonful (5 mL) for each 5 lb of body weight.

For the removal of large roundworms (ascarids) and hookworms, put one full teaspoonful (5 mL) for each 5 lb of dog's body weight in the animal's food bowl. To assure proper dosage, weigh animal prior to treatment. Dogs usually find this wormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is not necessary to withhold food from your dog prior to treatment.

The presence of large roundworms (ascarids) and hookworms should be confirmed by laboratory fecal examination. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2 to 4 weeks after first treatment. If your dog looks or acts sick, consult your veterinarian before treatment.

LOT C84569
EXP 10/01

Box Label

Box Top

4547

RFD[®]

(pyrantel pamoate)

**LIQUID
WORMER**

FOR PUPPIES AND DOGS

NADA #100-237, APPROVED BY FDA

Front Panel

4547

RFD[®]

(pyrantel pamoate)

**LIQUID
WORMER**

FOR PUPPIES AND DOGS

NADA #100-237, APPROVED BY FDA

Net Contents: 2 FL OZ (60 mL)

pfizer

Right Panel

DIRECTIONS FOR USE:
For maximum control and prevention of reinfection, it is recommended that puppies be treated at 2, 3, 4, 6, 8 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals to prevent T. canis reinfection. Administer 1 full teaspoonful (5 mL) for each 3 lb of body weight. For the removal of large roundworms (ascaris) and hookworms, put one full teaspoonful (5 mL) for each 3 lb of dog's body weight in the animal's food bowl. To assure proper dosage, weigh animal prior to treatment. Dogs usually find this wormer very palatable and will lick the dose from the bowl willingly. If there is reluctance to accept the dose, mix in a small quantity of dog food to encourage consumption. It is not necessary to withhold food from your dog prior to treatment.

The presence of large roundworms (ascaris) and hookworms should be confirmed by laboratory fecal examination. It is recommended that dogs maintained under conditions of constant exposure to worm infestation should have a follow-up fecal exam within 2-4 weeks after first treatment.

If your dog looks or acts sick, consult your veterinarian before treatment.

SHAKE WELL BEFORE USE

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

WARNING:
KEEP OUT OF REACH OF CHILDREN

PROOF OF PURCHASE

RFD 4547

Back Panel

4547

RFD[®]

(pyrantel pamoate)

**LIQUID
WORMER**

FOR PUPPIES AND DOGS

NADA #100-237, APPROVED BY FDA

Net Contents: 2 FL OZ (60 mL)

pfizer

Left Panel

The liquid wormer dogs LOVE

Easy to administer.

INDICATIONS FOR USE:
To prevent reinfection of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

For the removal of large roundworms (ascaris), *Toxocara canis* and *Toxascaris leonina* and hookworms, *Ancylostoma caninum* and *Uncinaria stenocephala* in dogs. The presence of these parasites should be confirmed by laboratory fecal examination. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

UPC BAR CODE
0-87219-04547-3

ACTIVE INGREDIENT
2.27 mg of pyrantel base as pyrantel pamoate per mL

MADE IN CANADA

Distributed by
North American Animal Health
Pfizer Inc, Lees Summit, MO 64081

00027

Box Bottom

LOT C84569
EXP 10/01