## NEMEX 2 NON-STERILE- pyrantel pamoate suspension Zoetis Inc.

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NEMEX®-2

NEMEX<sup>®</sup>-2 (pyrantel pamoate oral suspension) CANINE ANTHELMINTIC SUSPENSION

#### FOR ANIMAL USE ONLY

#### **DESCRIPTION**

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:

 $(\underline{E})$ -1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl) vinyl] pyrimidine 4,4' methylenebis [3-hydroxy-2-naphthoate] (1:1)

#### INDICATIONS AND USAGE

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.

#### **PRECAUTIONS**

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.

#### KEEP OUT OF REACH OF CHILDREN

#### DOSAGE AND ADMINISTRATION

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.

#### SAFETY AND EFFICACY STUDIES

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  $LD_{50}$  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 druginduced 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.

#### RECOMMENDED STORAGE

Store below 30°C (86°F).

#### **HOW SUPPLIED**

Nemex-2 is supplied in 2 fl. oz. (60 mL) and 16 fl. oz. (473 mL) bottles.

Approved by FDA under NADA # 100-237



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Distributed by: Zoetis Inc. Kalamazoo, MI 49007

#### PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

Dosage and Administration: 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 1 full teaspoonful (5 mL) for each 10 lb of body weight.

For the removal of large roundworms (ascarids) and hookworms, administer 1 full teaspoonful (5 mL) for each 10 lb of body weight. It is not necessary to withhold food prior to 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 2-4 weeks after first treatment.

Important: Shake Well Before Use

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Distributed by: Zoetis Inc. Kalamazoo, MI 49007

**Product of Spain** 

# Nemex®-2

(pyrantel pamoate oral suspension)

## Canine Anthelmintic Suspension

Active ingredient 4.54 mg of pyrantel base as pyrantel pamoate per mL.

For animal use only

Net Contents: 16 fl oz (473 mL)

Approved by FDA under NADA # 100-237

#### Indications and Usage:

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 30°C (86°F).



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#### NEMEX 2 NON-STERILE

pyrantel pamoate suspension

#### **Product Information**

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:54771-2934

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
pyrantel pamoate (UNII: 81BK194Z5M) (pyrantel - UNII:4QIH0N49E7)	pyrantel	4.54 mg in 1 mL

#### **Product Characteristics**

Color		Score	
Shape		Size	
Flavor	CARAMEL	Imprint Code	
Contains			

]	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:54771-2934-1	60 mL in 1 BOTTLE					
2	NDC:54771-2934-2	473 mL in 1 BOTTLE					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NADA	NADA100237	06/22/1979			

## **Labeler -** Zoetis Inc. (828851555)

Revised: 5/2020 Zoetis Inc.