

NEMEX™-2 SUSPENSION

Pfizer Animal Health

Parasiticide-Oral

(pyrantel pamoate) Canine Anthelmintic Suspension

NADA No.: 100-237

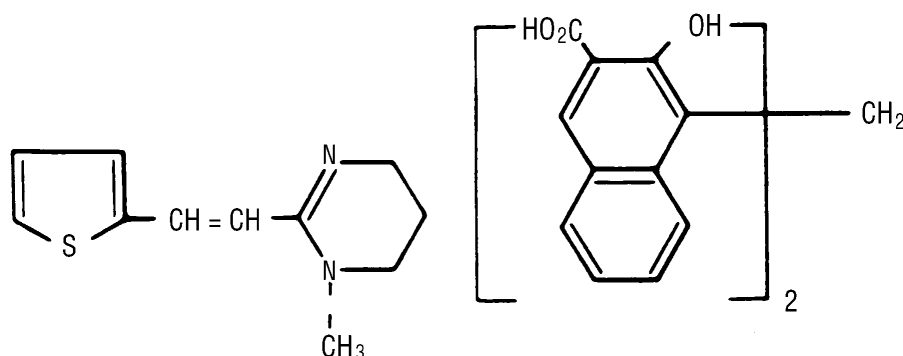
Active Ingredient(s): NEMEX™ is a suspension of pyrantel pamoate in a caramel-flavored vehicle. Each mL contains 4.54 mg of pyrantel base as pyrantel pamoate.

Indications: NEMEX™ Suspension is a highly palatable formulation intended as a single treatment for the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Anclystoma caninum* and *Uncinaria stenocephala*) in dogs and puppies.

NEMEX™ Suspension may also be used to prevent re-infection of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Pharmacology: 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:



The chemical name is (E)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl) vinyl] pyrimidine 4,4' methylenebis [3-hydroxy-2-naphtoate] (1:1).

Dosage and Administration: Administer one (1) full teaspoon (5 mL) for each 10

pounds of body weight (2.27 mg base per lb. of body weight). Although most dogs have been observed to find this formulation very palatable and are willingly consume it undiluted, it may be necessary to mix a small quantity of the formulation in the dog's normal ration to encourage consumption. Fasting prior to or after treatment is not necessary.

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

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 infection should have a follow-up fecal exam within two (2) to four (4) weeks after the first treatment.

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

Caution(s): The product is a suspension and as such will separate. To ensure uniform resuspension and to achieve proper dosage, it is extremely important that the product be shaken thoroughly before every use.

Keep out of the reach of children.

For veterinary use only.

Toxicology: One of the most significant features of NEMEX™ 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 pound of body weight, which indicates a therapeutic index in excess of 138x the recommended dosage. In subacute and chronic studies, significant morphological abnormalities could not be attributed to NEMEX™ when administered to dogs at daily dose rates of up to 94 mg base per pound 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 did not show drug-induced toxic effects. Included in these studies were nursing puppies, weaned pups, adults, pregnant bitches, and males at stud. Additional data have demonstrated the safe use of NEMEX™ (pyrantel pamoate) in:

1. dogs having heartworm infections and/or receiving medication for heartworms,
2. dogs exposed to organophosphate flea collars or flea/tick dip treatments, and
3. dogs undergoing concurrent treatment or medication at the time of worming such as immunization and antibacterial treatment.

Trial Data: Critical (worm count) studies in dogs demonstrated that NEMEX™ at the recommended dosage is highly efficacious against *T. lenoia* (99%), *T. canis* (85%), *A. caninum* (97%), and *U. stenocephala* (94%).

Presentation: Available in 2 fl. oz. (60 mL) and 1 pint (473 mL) bottles.

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.: 03691096