

Worm Protector 2X

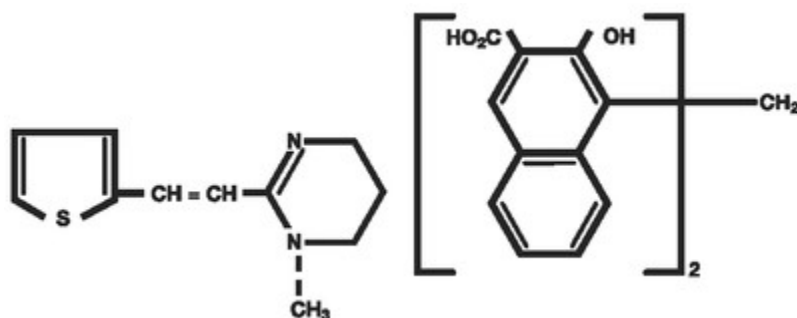
[pyrantel pamoate]

Canine Anthelmintic Suspension

ANADA #200-007, Approved by FDA

Worm Protector 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 USE: Worm Protector 2x 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.

Worm Protector 2x suspension may also be used to prevent reinfestation of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

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

DOSAGE AND ADMINISTRATION: Administer one full teaspoon (5mL) 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 willingly consume it undiluted, it may be necessary to mix a small quantity of 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 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 ENSURE UNIFORM RESUSPENSION AND TO ACHIEVE PROPER DOSAGE, **IT IS EXTREMELY IMPORTANT THAT THE PRODUCT BE SHAKEN THOROUGHLY BEFORE EVERY USE.**

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

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

SAFETY: One of the most outstanding and significant features of pyrantel pamoate 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 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 pound of body weight (40 x) 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 (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.