

## FREEDOM OF INFORMATION SUMMARY

### I. GENERAL INFORMATION

#### A. File Number

ANADA 200-248

#### B. Sponsor

Phoenix Scientific, Inc.

#### C. Proprietary Name

Pyrantel Pamoate Suspension - 4.54mg, Pyrantel Pamoate Suspension - 2.27mg

#### D. Established Name

Pyrantel Pamoate USP

#### E. Dosage Form

Oral suspension

#### F. Amount of Active Ingredient

Each mL contains: 4.54 mg Pyrantel (base) as Pyrantel Pamoate 2.27mg Pyrantel (base) as Pyrantel Pamoate

#### G. How Supplied

2 oz and 16 oz HDPE bottles

#### H. Dispensing Status

OTC

#### I. Dosage Regimen

##### **Labeled Dosage:** 4.54 mg/mL

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 one full teaspoonful (5mL) for each 10 lb of body weight.

##### **Labeled Dosage:** 4.54 mg/mL

For the removal of large roundworms (ascarids) and hookworms. Administer one full teaspoonful (5mL) for each 10 lb of body weight. It is not necessary to withhold food 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 recommended that dogs maintained under conditions of constant exposure to worm infection should have a follow-up fecal exam within 2 to 4 weeks after first treatment.

**Labeled Dosage:** 2.27 mg/mL

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 one full teaspoonful (5mL) for each 5 lb of body weight.

For the removal of large roundworms (ascarids) and hookworms. Administer one full teaspoonful (5mL) for each 5 lb of body weight. It is not necessary to withhold food 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 recommended that dogs maintained under conditions of constant exposure to worm infection should have a follow-up fecal exam within 2 to 4 weeks after first treatment.

**J. Route of Administration**

Oral

**K. Species/Class**

Puppies and Dogs (ONLY)

**L. Indication**

To prevent reinfection 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.

**II. EFFECTIVENESS AND TARGET ANIMAL SAFETY**

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. Approval of an ANADA requires that the sponsor show that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA Policy Letter, 55 FR 24645, June 18, 1990; Bioequivalence Guidance, 1996, 61 FR 26182, May 24, 1996).

Based on the formulation characteristics of the generic product, Phoenix Scientific Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Pyrantel Pamoate Oral Suspension. The generic product is administered as an oral suspension and contains the same active and inactive ingredients in the same concentration as the pioneer product.

### III. HUMAN FOOD SAFETY

The product is labeled for use in dogs only, not a food producing animal. Therefore no human food safety information is required

**Human Safety Relative to Possession, Handling and Administration:** Labeling contains adequate caution/warning statements.

### IV. 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 Pyrantel Pamoate Suspension when used under its proposed conditions of use, is safe and effective for the labeled indications.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.