

HFA-305

Date of Approval: AUG 28 2003

FREEDOM OF INFORMATION (FOI) SUMMARY

**ORIGINAL ABBREVIATED NEW ANIMAL DRUG
APPLICATION (ANADA)**

ANADA 200-265

**Praziquantel Tablets
(praziquantel)
34 mg/tablet**

Cestocide for Dogs and Puppies

**For the removal of the following cestodes: *Dipylidium caninum*,
Taenia pisiformis, *Echinococcus granulosus* and for the removal and
control of *Echinococcus multilocularis*.**

Sponsored by:

**Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64503**

FOIS 1

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-265
- b. Sponsor: Phoenix Scientific, Inc.
3915 S. 48th Street Terrace
St. Joseph, MO 64503
- Drug Labeler Code: 059130
- c. Established Name: Praziquantel
- d. Proprietary Name: Praziquantel Tablets
- e. Dosage Form: Tablets
- f. How Supplied: 50, 150, or 500 tablets in HDPE bottles
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: 34 mg of praziquantel per tablet
- i. Route of Administration: Oral
- j. Species/Class: Dogs and puppies
- k. Recommended Dosage: Tablets may be administered directly per os or crumbled and mixed with feed:

5 lbs. & under	0.5 tablet
6-10 lbs.	1 tablet
11-15 lbs.	1.5 tablets
16-30 lbs.	2 tablets
31-45 lbs.	3 tablets
46-60 lbs.	4 tablets
Over 60 lbs.	5 tablets max

Not intended for use in puppies less than 4 weeks of age. FASTING IS NEITHER NECESSARY NOR RECOMMENDED.

1. Pharmacological Category: Anthelmintic (cestocide)

m. Indications:

For the removal of *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*.

n. Pioneer Product:

DRONCIT Canine Cestocide Tablets (praziquantel);
NADA 111-798; Bayer HealthCare LLC, Animal
Health Division

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.

To show that this generic product is safe and effective for its intended use an *in vivo* bioequivalence study was conducted. A summary of this study follows:

Title: Serum Bioequivalence of Generic and Pioneer Praziquantel Oral Tablets in the Dog.

Study Location: CAVL, Inc.
9602 S. Washington Street
RR 7, Box 594
Amarillo, TX 79118

Trial Design: Two Period Crossover

This study used twenty-four, 12 male and 12 female, healthy mixed breed dogs, between 1 and 3 years of age at the time of selection for the study and weighing from 31 to 45 lb. Dogs were segregated by sex and ranked by initial body weight (highest to lowest) within each sex. Three blocks were constructed around the ranked order of animals. Each block contained 4 males and 4 females.

Treatment consisted of a single administration of three (3) 34 mg tablets (102 mg) of generic and pioneer praziquantel per os. Using a two period crossover experimental design, each group of 12 dogs for period 1 received either the sponsor's test formulation or the reference formulation product. There was a 48 hour washout interval between the two periods of the crossover design. After the washout interval (period 2) the groups switched products.

Blood samples for each animal, for each period of the study were taken at the following times, 0 hour and (hours after drug administration); 0.25, 0.5, 0.75, 1, 1.25, 1.5, 1.75, 2, 2.5, 3, 4, 5, 6, 8, 12, and 24 hours (17 samples/animal/treatment period). Approximately 48 hours after the first treatment, animals were dosed with the alternate product and the blood collections repeated

during the second treatment period. Serum samples were submitted to the designated laboratory for praziquantel analysis at the completion of the study. Each sample was analyzed on an HPLC system equipped with an ultraviolet detector. The results were calculated using a linear regression analysis.

The following table reflect the data of the assayed praziquantel serum levels in the blood of the test animals from the 0 hour sample through the 24 hour sample as statistically analyzed with an analysis of variance procedure following the 1996 Bioequivalence Guideline.

Variable	Phoenix mean	Bayer Mean	Lower	Upper
Log _e (Area under Curve)	7.452	7.449	-7.5%	8.76%
Log _e (Maximum Concentration)	6.33	6.22	-0.09%	25.42%

Both variables, the logarithmic area under the curve and logarithmic maximum concentration, satisfied the bioequivalence criteria. Therefore, the study objective to determine the bioequivalence of generic and pioneer praziquantel tablets by serum bioequivalence was achieved.

3. *HUMAN SAFETY:*

This drug is indicated for use only in dogs and puppies, which are non-food animals. Since 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 warning statements are provided on the product labeling as follows: **“Keep out of the reach of children. Not for human use.”**

4. *AGENCY CONCLUSIONS:*

This ANADA filed 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 Praziquantel Tablets, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. *ATTACHMENTS:*

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

Generic Labeling for ANADA 200-265:

Praziquantel Tablets (praziquantel)

1 – 50 tablet container label; 1 – 150 tablet container label; 1 – 500 tablet container label

1 – package insert

FOI Summary
ANADA 200-265

Pioneer Labeling for NADA 111-798:

DRONCIT Canine Cestocide Tablets (praziquantel)

1 – 50 tablet container label; 1 – 150 tablet container label

1 – package insert

DOSAGE AND ADMINISTRATION:
Administer orally to dogs and puppies* as follows:

5 pounds and under	—	1/2 tablet
6-10 pounds	—	1 tablet
11-15 pounds	—	1 1/2 tablets
16-30 pounds	—	2 tablets
31-45 pounds	—	3 tablets
46-60 pounds	—	4 tablets
Over 60 pounds	—	5 tablets max.

*Not intended for use in puppies less than 4 weeks of age.

Tablets may be given directly or crumbled and offered with the feed **FASTING IS NEITHER NECESSARY NOR RECOMMENDED.**

For the removal of *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*.
801004 Iss. 5-03

NDC 59130-684-15

Praziquantel Tablets

Cestocide for Dogs and Puppies

34 mg

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

ANADA 200-265, Approved by FDA

NET CONTENTS: 50 Tablets



Read package insert before using this drug.

EACH TABLET CONTAINS: 34 mg praziquantel.

WARNING: Keep Out of Reach of Children. Not for human use.

Store at controlled room temperature 20°-25°C (68°-77°F)

TAKETIME  **OBSERVE LABEL DIRECTIONS**

Manufactured by Phoenix Scientific, Inc. St. Joseph, MO 64503

Lot No.

Exp. Date



DOSAGE AND ADMINISTRATION:
Administer orally to dogs and puppies* as follows:

5 pounds and under — 1/2 tablet
6-10 pounds — 1 tablet
11-15 pounds — 1 1/2 tablets
16-30 pounds — 2 tablets
31-45 pounds — 3 tablets
46-60 pounds — 4 tablets
Over 60 pounds — 5 tablets max.

*Not intended for use in puppies less than 4 weeks of age.

Tablets may be given directly or crumbled and offered with the feed. **FASTING IS NEITHER NECESSARY NOR RECOMMENDED.**



801004

Iss. 5-03

NDC 59130-684-20

Praziquantel Tablets

Cestocide for Dogs and Puppies

34 mg

For the removal of *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

ANADA 200-265, Approved by FDA
NET CONTENTS: 150 Tablets

AmTech
Group, Inc.

Read package insert before using this drug.

EACH TABLET CONTAINS: 34 mg praziquantel.

WARNING: Keep Out of Reach of Children. Not for human use.

Store at controlled room temperature 20°-25°C (68°-77°F)



Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

Lot No.

Exp. Date

DOSAGE AND ADMINISTRATION: NDC 59130-684-21
Administer orally to dogs and puppies* as follows:

5 pounds and under	—	1/2 tablet
6-10 pounds	—	1 tablet
11-15 pounds	—	1 1/2 tablets
16-30 pounds	—	2 tablets
31-45 pounds	—	3 tablets
46-60 pounds	—	4 tablets
Over 60 pounds	—	5 tablets max.

*Not intended for use in puppies less than 4 weeks of age.

Tablets may be given directly or crumbled and offered with the feed. **FASTING IS NEITHER NECESSARY NOR RECOMMENDED.**



801004

Iss. 5-03

Praziquantel Tablets

Cestocide for Dogs and Puppies
34 mg

For the removal of *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

ANADA 200-265, Approved by FDA

NET CONTENTS: 500 Tablets

Amtech[®]
Group, Inc.

Read package insert before using this drug.

EACH TABLET CONTAINS: 34 mg praziquantel.

WARNING: Keep Out of Reach of Children. Not for human use.

Store at controlled room temperature 20°-25°C (68°-77°F)

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

TAKE TIME



OBSERVE LABEL
DIRECTIONS

Lot No.

Exp. Date

ANADA 200-265, Approved by FDA

AM

Praziquantel Tablets

Cestocide for Dogs and Puppies

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Each tablet contains 34 mg praziquantel.

DESCRIPTION: Praziquantel Tablets are sized for easy oral administration to either adult dogs or puppies. The tablets may be crumbled and mixed with the feed.

INDICATIONS: Praziquantel Tablets are indicated for the removal of the following canine cestodes: *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*.

ACTION: Praziquantel Tablets are absorbed, metabolized in the liver and excreted in the bile. Upon entering the digestive tract from the bile, cestocidal activity is exhibited.¹ Following exposure to praziquantel, the tapeworm loses its ability to resist digestion by the mammalian host.

Because of this, whole tapeworms, including the scolex, are very rarely passed after administration of praziquantel. In many instances only disintegrated and partially digested pieces of tapeworms will be seen in the stool. The majority of tapeworms are digested and are not found in the feces.

USE DIRECTIONS: Praziquantel Tablets may be administered directly per os or crumbled and mixed with the feed. The recommended dosage of praziquantel varies according to body weight. Smaller animals require a relatively larger dosage because of their higher metabolic rate. The optimum dose for each individual animal will be achieved by utilizing the following dosage schedule:

Dogs and Puppies*	
5 lbs. and under	1/2 tablet
6-10 lbs.	1 tablet
11-15 lbs.	1 1/2 tablets
16-30 lbs.	2 tablets
31-45 lbs.	3 tablets
46-60 lbs.	4 tablets
Over 60 lbs.	5 tablets max

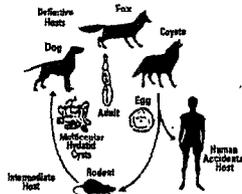
* Not intended for use in puppies less than 4 weeks of age.

FASTING: The recommended dosage of praziquantel is not affected by the presence or absence of food in the gastrointestinal tract, therefore, **FASTING IS NEITHER NECESSARY NOR RECOMMENDED.**

RETREATMENT: For those animals living where reinfections are likely to occur, clients should be instructed in the steps to optimize prevention, otherwise, retreatment may be necessary. This is true in cases of *Dipylidium caninum* where reinfection is almost certain to occur if fleas are not removed from the animal and its environment. In addition, for control of *Echinococcus multilocularis*, a program of regular treatment every 21 to 26 days may be indicated (see *E. multilocularis* section below).

ECHINOCOCCUS MULTILOCULARIS: *Echinococcus multilocularis* is a tapeworm species ordinarily considered to be found in wild canids, including foxes, coyotes and wolves. The parasite has also been identified in domestic dogs and cats and potentially is a serious public health concern by involving humans as accidental intermediate hosts.

The life cycle of the parasite is based on a predator-prey relationship, as depicted below.



The adult tapeworm is small (1-4 mm) and resides in the intestinal tract of the definitive host (wild or domestic canids). Eggs from the adult tapeworm are shed in the feces of the infected canid. Rodents such as mice and voles serve as the intermediate host for *E. multilocularis*. Eggs ingested by rodents develop in the liver, lungs and other organs to form multilocular cysts. The life cycle is completed after a canid consumes a rodent infected with cysts. After ingestion of an infected rodent, larvae contained within the cyst develop into adult tapeworms in the intestinal tract of the canid. Eggs may begin to be passed in the feces of the canid approximately 28 days later.

This parasite poses a serious public health problem because of the possibility for human involvement in the life cycle. If eggs shed by an infected canid are accidentally ingested, a highly pathogenic condition (Alveolar Hydatid Disease) results from development of the cyst stage in humans. The original geographic distribution of *E. multilocularis* was primarily confined to northern areas of North America. Current evidence indicates migration of the parasite well into the continental United States.^{2,3}

Domestic dogs living in *E. multilocularis* endemic areas that roam freely with the opportunity to catch wild rodents are at risk for infection. Pet owners should be

advised on how to minimize this risk. Proper restraint of roaming dogs should be encouraged, along with regular treatment with Praziquantel Tablets, following the established aforementioned dosing schedule and the following precautions.

Additional information on the life cycle and epidemiology of this parasite is available in veterinary parasitology texts.^{4,5}

DIAGNOSIS: Diagnosis of *E. multilocularis* in canids is difficult. The adult tapeworm produces no clinical signs of infection. Tapeworm segments (proglottids) are usually not observed in the feces. *E. multilocularis* eggs, observed using microscopic fecal examination procedures, are similar in appearance to the common taeniid species of canids such as *Taenia pisiformis*.

Assistance in the diagnosis of *E. multilocularis* may be available from a state veterinary diagnostic laboratory. Additional information regarding areas where *E. multilocularis* is suspected or has been confirmed may be obtained from area veterinary schools or the Centers for Disease Control in Atlanta, GA.

TREATMENT: Dogs infected with *E. multilocularis* should be treated to prevent exposure of humans to infective eggs and to reduce perpetuation of the parasite's life cycle.

The dosage of Praziquantel Tablets for removal of *E. multilocularis* is the same as that indicated for the removal of the other tapeworm species listed on the label. Laboratory efficacy studies have demonstrated the recommended dosage is 100% efficacious for removal of this tapeworm.

Under condition of continual exposure to wild rodents, retreatment of the dog at 21-26 day intervals is recommended to prevent the shedding of infectious eggs.

PRECAUTIONS: Strict hygienic precautions should be taken when handling dogs or feces suspected of harboring *E. multilocularis*. Infected dogs treated for the first time with Praziquantel Tablets and dogs treated at intervals greater than 28 days may shed eggs in the feces after treatment. The animal should be held in the clinic during this interval and all feces should be incinerated or autoclaved. If these procedures are not possible, the eggs can be destroyed by soaking the feces in a sodium hypochlorite (bleach) solution of 3.75% or greater.⁶ All areas where the animal was maintained or in contact with should be thoroughly cleaned with sodium hypochlorite and allowed to dry completely before reuse.

OVERDOSAGE: The safety index has been derived from controlled safety evaluations, clinical trials and prior approved use in foreign countries. Dosages of 5 times the labeled rate at 14 day intervals to dogs as young as 4 weeks did not produce clinical signs of toxicity. No significant clinical chemistry, hematological, cholinesterase, or histopathological changes occurred. Symptoms of gross overdosage include vomiting, salivation, diarrhea and depression.

CONTRAINDICATIONS: There are no known contraindications to the use of praziquantel in dogs.

PREGNANCY: Praziquantel has been tested in breeding and pregnant dogs. No adverse effects were noted.

ADVERSE REACTIONS: Seven instances (3.2%) of either vomiting, anorexia, lethargy or diarrhea were reported during the field trials in which 218 dogs were administered praziquantel tablets. The investigators rated these as non-significant.

WARNING: Keep out of the reach of children. Not for human use.

HOW SUPPLIED: Bottles of 50, 150 and 500 scored tablets. Each scored tablet contains 34 mg praziquantel.

REFERENCES:

- Andrews, P., Pharmacokinetic Studies with Droncit® in Animals Using a Biological Assay, *Veterinary Medical Review*, 2/76, pg. 154-165.
- Hildreth, M.B., Johnson, M.D. and Kozacos K.R., 1991. A Zoonosis of Increasing Concern in the United States. *Compendium for Cont Ed*, 13(5) 727-740.
- Lieby, P.D., Carney, W.P., and Woods, C.E., 1970. Studies on Sylvatic Echinococcosis, III. Host Occurrence and Geographic Distribution of *Echinococcus multilocularis* in the North Central United States. *J Parasit* 56 (6) 1141-1150.
- Georgi, J.R. and Georgi M.E., 1990. *Parasitology for Veterinarians*. W.B. Saunders Co. 118-138.
- Soulsby, E.J.L., 1982. *Helminths, Arthropods and Protozoa of Domesticated Animals*. 7th Edition. Lea & Febiger. 118-138.
- Craig, P.S. and McPharson, C.N.L., 1988 Sodium Hypochlorite as an Ovicide for *Echinococcus*. *Ann Trop Med and Parasit* 82 (2) 211-213.

Store at controlled room temperature 20°-25° C (68°-77° F).

801004

Iss. 5-03

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

NADA 111-798, Approved by FDA

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

EACH TABLET CONTAINS: 34 mg praziquantel.

DOSAGE AND ADMINISTRATION: Administer orally to dogs as follows:

- 5 pounds and under - 1/2 tablet
- 6-10 pounds - 1 tablet
- 11-15 pounds - 1 1/2 tablets
- 16-30 pounds - 2 tablets
- 31-45 pounds - 3 tablets
- 46-60 pounds - 4 tablets
- Over 60 pounds - 5 tablets max.

Tablets may be given directly or crumbled and offered with the feed. FASTING IS NEITHER NECESSARY NOR RECOMMENDED.

1828

71018280, R.10

▲ OPEN AT PERFORATION ▲



130113
JAN 99

Lot No.
Exp. Date

Droncit Tablets
NADA 111-798
34 mg Canine Tablets
150 Tab Bottle
Label/Insert Combo

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

EACH TABLET CONTAINS:
34 mg praziquantel.

DOSAGE AND ADMINISTRATION: Administer orally to dogs as follows:

5 lbs. and under	1/2 tablet
6 - 10 lbs.	1 tablet
11 - 15 lbs.	1 1/2 tablets
16 - 30 lbs.	2 tablets
31 - 45 lbs.	3 tablets
46 - 60 lbs.	4 tablets
Over 60 lbs.	5 tablets max.

Tablets may be given directly or crumbled and offered with the feed.

FASTING IS NEITHER NECESSARY NOR RECOMMENDED.

1860 71018607

Lot No.
Exp. Date

▲ OPEN AT PERFORATION ▲



Droncit® (praziquantel)

Canine Cestocide Tablets

Each tablet contains 34 mg praziquantel.

DESCRIPTION: Droncit® (praziquantel) Canine Cestocide Tablets are sized for easy oral administration to either adult dogs or puppies. The tablets may be crumbled and mixed with the feed.

INDICATIONS: Droncit® (praziquantel) Canine Cestocide

Tablets are indicated for the removal of the following canine cestodes: *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*.

ACTION: Droncit® (praziquantel) is absorbed, metabolized in the liver and excreted in the bile. Upon entering the digestive tract from the bile, cestocidal activity is exhibited.¹ Following exposure to praziquantel, the tapeworm loses its ability to resist digestion by the mammalian host.

Because of this, whole tapeworms, including the scolex, are very rarely passed after administration of praziquantel. In many instances only disintegrated and partially digested pieces of tapeworms will be seen in the stool. The majority of tapeworms are digested and are not found in the feces.

USE DIRECTIONS: Droncit® (praziquantel) Canine Cestocide Tablets may be administered directly per os or crumbled and mixed with the feed. The recommended dosage of praziquantel varies according to body weight. Smaller animals require a relatively larger dosage

because of their higher metabolic rate. The optimum dose for each individual animal will be achieved by utilizing the following dosage schedule:

Dogs and Puppies*

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46-60 lbs.	4 tablets
Over 60 lbs.	5 tablets max

* Not intended for use in puppies less than 4 weeks of age.

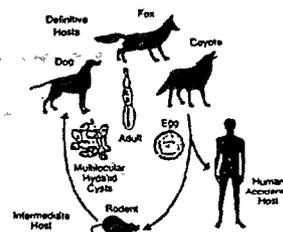
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This parasite poses a serious public health problem because of the possibility for human involvement in the life cycle. If eggs shed by an infected canid are accidentally ingested, a highly pathogenic condition (Alveolar Hydatid Disease) results from development of the cyst stage in humans.

The original geographic distribution of *E. multilocularis* was primarily confined to northern areas of North America. Current evidence indicates migration of the parasite well into the continental United States.^{2,3} Domestic dogs living in *E. multilocularis* endemic areas that

roam freely with the opportunity to catch wild rodents are at risk for infection. Pet owners should be advised on how to minimize this risk. Proper restraint of roaming dogs should be encouraged, along with regular treatment with Droncit tablets, following the established aforementioned dosing schedule and the following precautions.

Additional information on the life cycle and epidemiology of this parasite is available in veterinary parasitology texts.^{4,5} **DIAGNOSIS:** Diagnosis of *E. multilocularis* in canids is difficult. The adult tapeworm produces no clinical signs of infection. Tapeworm segments (proglottids) are usually not

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TREATMENT: Dogs infected with *E. multilocularis* should

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Under condition of continual exposure to wild rodents, retreatment of the dog at 21-26 day intervals is recommended to prevent the shedding of infectious eggs.

PRECAUTIONS: Strict hygienic precautions should be taken

when handling dogs or feces suspected of harboring *E. multilocularis*. Infected dogs treated for the first time with Droncit tablets and dogs treated at intervals greater than 28 days may shed eggs in the feces after treatment. The animal should be held in the clinic during this interval and all feces should be incinerated or autoclaved. If these procedures are not possible, the eggs can be destroyed by soaking the feces in a sodium hypochlorite (bleach) solution of 3.75% or greater.⁶ All areas where the animal was maintained or in contact with should be thoroughly cleaned with sodium hypochlorite and allowed to dry completely before reuse.

OVERDOSAGE: The safety index has been derived from controlled safety evaluations, clinical trials and prior approved use in foreign countries. Dosages of 5 times the labeled rate at 14 day intervals to dogs as young as 4 weeks did not produce clinical signs of toxicity. No significant clinical chemistry, hematological, cholinesterase, or histopathological changes occurred. Symptoms of gross overdosage include vomiting, salivation, diarrhea and depression.

CONTRAINDICATIONS: There are no known contraindications to the use of praziquantel in dogs.

PREGNANCY: Droncit® (praziquantel) has been tested in breeding and pregnant dogs. No adverse effects were noted.

ADVERSE REACTIONS: Seven instances (3.2%) of either vomiting, anorexia, lethargy or diarrhea were reported during the field trials in which 218 dogs were administered Droncit® Canine Cestocide Tablets. The investigators rated these as non-significant.

WARNING: Keep out of the reach of children. Not for human use.

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

HOW SUPPLIED: Bottle of 50, and 150 scored tablets. Each scored tablet contains 34 mg praziquantel.

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- ³ Lieby, P.D., Carney, W.P., and Woods, C.E., 1970. Studies on Sylvatic Echinococcosis. III. Host Occurrence and Geographic Distribution of *Echinococcus multilocularis* in the North Central United States. *J Parasit* 56 (6) 1141-1150.
- ⁴ Georgi, J.R. and Georgi M.E., 1990. *Parasitology for Veterinarians*. W.B. Saunders Co. 118-138
- ⁵ Soulsby, E.J.L., 1982. *Helminths, Arthropods and Protozoa of Domesticated Animals*. 7th Edition. Lea & Febiger. 118-138.
- ⁶ Craig, P.S. and McPharson, C.N.L., 1988 Sodium Hypochlorite as an Ovicide for *Echinococcus*. *Ann Trop Med and Parasit* 82 (2) 211-213.

Droncit is a registered TM of the parent company of Bayer AG, Leverkusen.

Product Code 1828 — 50 Tablets
Code 1860 — 150 Tablets
Made in U.S.A.

NADA 111-798, Approved by FDA

Bayer 

Bayer Corporation, Agriculture Division,
Animal Health
Shawnee Mission, Kansas 66201 U.S.A.

June, 1995