

HFA-305

Date of  
Approval            OCT 16 2002

## FREEDOM OF INFORMATION SUMMARY

Original ANADA 200-176

PRAZITECH™ Injection

(Dogs and cats)

Sponsored by:

Phoenix Scientific, Inc.  
3915 S. 48th St. Terrace  
St. Joseph, MO 64503

FOIS

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

ANADA:	200-176
Sponsor:	Phoenix Scientific, Inc. 3915 S. 48th ST. Terrace St. Joseph, MO 64503
Generic Name:	Praziquantel
Trade Name:	PRAZITECH™ Injection
Dosage Form:	Injectable
How Supplied:	10 & 50 mL bottles
How Dispensed:	Rx
Amount of Active Ingredients:	56.8 mg/mL praziquantel
Route of Administration:	IM or SC
Species:	Dogs and cats
Pharmacological Category:	Cestocide
Indication and Dosage:	Dogs: 5 lbs. and under-0.3 mL 6-10 lbs-0.5 mL 11-25 lbs. -1.0 mL Cats: Under 5-lbs. -0.2 mL 5-10 lbs-0.4 mL 11 lbs. and over 0.6 mL maximum

Praziquantel Injection is indicated for the removal of the following canine and/or feline cestodes.

Dogs: *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and *Echinococcus multilocularis*.

Cats: *Taenia taeniaeformis* and *Dipylidium caninum*.

Pioneer Product/  
Listed Product:

Droncit® Injectable  
NADA 111-607  
Bayer Corporation

## 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) of 1988, 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 and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645 June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for PRAZITECH™ Injection (praziquantel). The generic and pioneer products are solutions that contain the same active and inactive ingredients in the same concentrations.

3. HUMAN SAFETY:

PRAZITECH™ Injection is intended for use only in dogs and cats, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application 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 PRAZITECH™, when used under the proposed conditions of use, is safe and effective for the labeled indications.

5. LABELING:

Attachments:

Pioneer Labeling:

Package Insert for Droncit®  
10 mL & 50 mL bottle labels

Generic Labeling:

Package Insert for PRAZITECT™  
10 mL & 50 mL bottle labels

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration  
Freedom of Information Staff (HF1-35)  
5600 Fishers Lane  
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.

ITEM

**Droncil®**  
(praziquantel)  
Injectable Oestride For Dogs And Cats

500 mg/mL Solution  
CONTAINS 10 mL praziquantel 500 mg/mL  
solution. Each 10 mL contains 500 mg  
praziquantel (100 mg/mL).

**Bayer** 10 mL  
Bayer Corporation, Agriculture Division, Animal Health  
Shawnee Mission, Kansas 66201 U.S.A.

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

**DIRECTIONS:** For I.M. or S.C.  
injection.

**Dogs:** 5 lbs and under-0.3 mL,  
6-10 lbs-0.5 mL, 11-25 lbs-  
1.0 mL, Over 25 lbs-0.2 mL/lb  
wt. (max. 3 mL).

**Cats:** Under 5 lbs-0.2 mL,  
5-10 lbs-0.4 mL, 11 lbs. and over-  
0.6 mL maximum.

Read package insert before using  
this drug. 183  
NADA 111-607, APPROVED BY FDA

71018310, R-8

Lot  
Exp. **SAMPLE**

ITEM 3

**Droncit®**  
(praziquantel)  
Injectable Cestocide For Dogs And Cats

50 mL

**Bayer**

Bayer Corporation  
Agriculture Division, Animal Health  
Shewee Mission, Kansas 66201 U.S.A.  
NADA 111-807, Approved by FDA

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

**DIRECTIONS:** For I.M. or S.C. Injection.

**Dogs:** 5 lbs. and under—0.3 mL, 6-10 lbs.—0.5 mL, 11-25 lbs.—1.0 mL, Over 25 lbs.—0.2 mL/5 lbs. bwt. (max. 3 mL)

**Cats:** Under 5 lbs.—0.2 mL, 5-10 lbs.—0.4 mL, 11 lbs. and over—0.6 mL maximum

Read package insert before using this drug.

1837

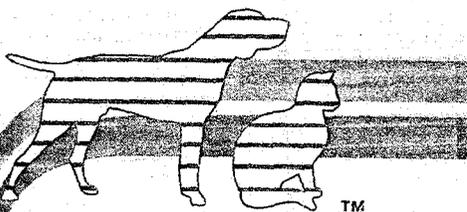
71018370, R. 4

**SAMPLE**

Lot Exp.

# Droncit® (praziquantel)

Injectable Cestocide  
For Dogs And Cats



56.8 mg/mL Solution

#### DESCRIPTION:

Droncit Injectable Cestocide is a clear solution containing 56.8 milligrams of praziquantel per mL which has been formulated for subcutaneous or intramuscular use in dogs and cats for removal of cestodes (tapeworms).

#### INDICATIONS:

Droncit (praziquantel) Injectable Cestocide is indicated for the removal of the following canine and/or feline cestodes. Dogs: *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*. Cats: *Taenia taeniaeformis* and *Dipylidium caninum*.

#### ACTION:

Droncit (praziquantel) is absorbed, metabolized in the liver and excreted via the bile into the digestive tract where its cestocidal activity is exerted.<sup>1</sup> 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. It is common to see only disintegrated and partially digested pieces of tapeworms in the stool. The majority of tapeworms killed are digested and are not found in the feces.

#### USE DIRECTIONS:

Droncit (praziquantel) Injectable Cestocide may be administered by either the subcutaneous or intramuscular route to dogs and cats. The recommended dosage of praziquantel varies according to body weight. Smaller animals require a relatively larger dosage. The optimum dosage for each individual animal will be achieved by utilizing the following dosage schedule.

Bayer

Bayer Corporation  
Agriculture Division, Animal Health  
Shawnee Mission, Kansas 66201 U.S.A.  
NADA 111-607, Approved by FDA

#### DOGS AND PUPPIES†

Dogs:	
5 lbs. and under	0.3 mL
6-10 lbs.	0.5 mL
11-25 lbs.	1.0 mL
over 25 lbs.	0.2 mL / 5 lbs. body weight to a maximum of 3 mL

† Not intended for use in puppies less than four (4) weeks of age.

#### CATS AND KITTENS††

Cats:	
Under 5 lbs.	0.2 mL
5-10 lbs.	0.4 mL
11 lbs. and over	0.6 mL maximum

†† Not intended for use in kittens less than six (6) 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.

#### ADMINISTRATION:

Droncit (praziquantel) Injectable Cestocide may be administered by either the subcutaneous or intramuscular route to dogs and cats. The intramuscular route may be preferred in dogs due to a brief period of pain that occasionally follows subcutaneous administration.

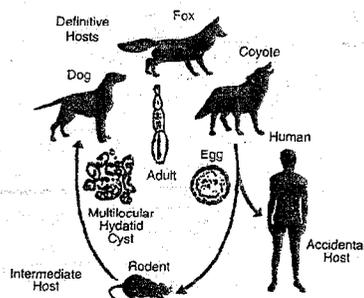
Anaphylactoid reactions were not observed in clinical trials. However, as with any drug an anaphylactoid reaction can occur with this product and should be treated symptomatically if it occurs.

#### 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 above.

The adult tapeworm is small (1-4mm) 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 the infected rodent, larvae within

Droncit



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Droncit



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the cyst develop to 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.<sup>2,3</sup>

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 Injectable solution, following the dosing schedule aforementioned and precautions indicated below.

Additional information on the life cycle and epidemiology of this parasite is available in veterinary parasitology texts.<sup>4,5</sup>

#### 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 Droncit Injectable solution 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 Droncit Injectable solution 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.<sup>6</sup> 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 signs of clinical toxicity following either intramuscular or subcutaneous injections. No significant clinical chemistry, hematological, cholinesterase or histopathological changes occurred. Dosages of 5 times the labeled rate at 14 day intervals to kittens as young as 5 1/2 weeks did not produce signs of clinical toxicity following either intramuscular or subcutaneous injections. Symptoms of overdosage (33.8 to 40 times the labeled

dosage rate) in adult dogs included vomiting, excessive salivation and depression, but no deaths. Symptoms of overdosage (10 to 20 times the labeled dosage rate) in adult cats included vomiting, depression, muscle tremors and incoordination. Deaths occurred in 5 of 8 cats treated subcutaneously and in all 8 injected intramuscularly at doses greater than 20 times the label rate.

#### CONTRAINDICATIONS:

There are no known contraindications to the use of praziquantel.

#### PREGNANCY:

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

#### ADVERSE REACTION:

Mild side effects were observed in 18 of 189 dogs (9.5%) and 8 of 85 cats (9.4%) administered Droncit Injectable in field trials. For dogs the majority of these were described as brief pain responses following injections to larger dogs (weighing over 50 lbs.). Two dogs exhibited a brief period of mild vomiting and/or drowsy or staggering gait. The eight cats exhibited either diarrhea, weakness, vomiting, salivation, sleepiness, burning on injection and/or a temporary lack of appetite. Local irritation or swelling at the site of subcutaneous injections have been reported for cats.

#### CAUTION:

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

#### HOW SUPPLIED:

Code:	1831	10 mL vial
	1837	50 mL vial

#### REFERENCES:

- 1 Andrews, P., Pharmacokinetic Studies with DRONCIT® in Animals Using a Biological Assay. *Veterinary Medical Review*, 2/76, pg. 154-165.
- 2 Hildreth, M.B., Johnson, M.D. and Kazacos K.R., 1991. A Zoonosis of Increasing Concern in the United States. *Compendium for Cont Ed*, 13(5) 727-740.
- 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 Trademark of the Parent Company of Bayer AG, Leverkusen.



**CONTAINS PER mL:** Praziquantel 56.8 mg, benzyl alcohol 75 mg, chlorobutanol hydrous 5 mg in propylene glycol q.s.  
Store between 15° and 30°C (59° and 86°F)

TAKE TIME  OBSERVE LABEL DIRECTIONS

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

**NET CONTENTS: 50 mL**  
**PraziTech™ Injection**  
(praziquantel)  
Injectable Cestocide For Dogs and Cats  
56.8 mg/mL Solution

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

ANADA 200-175. Approved by FDA

**DIRECTIONS:** For I.M. or S.C. Injection.  
**Dogs:** 5 lbs. and under-0.3 mL  
6-10 lbs.-0.5 mL  
11-25 lbs.-1.0 mL  
Over 25 lbs.-0.2 mL/5 lbs. bwt. (max. 3 mL)  
**Cats:** Under 5 lbs.-0.2 mL  
5-10 lbs.-0.4 mL  
11 lbs. and over-0.6 mL maximum

Read package insert before using this drug.

Lot No.  
Exp. Date

  
3 59130 65511 7  
600066 Iss. 8-02



**CONTAINS PER mL:** Praziquantel 56.8 mg, benzyl alcohol 75 mg, chlorobutanol hydrous 5 mg in propylene glycol q.s.  
Store between 15° and 30°C (59° and 86°F)

TAKE TIME  OBSERVE LABEL DIRECTIONS

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

**NET CONTENTS: 50 mL**  
**PraziTech™ Injection**  
(praziquantel)  
Injectable Cestocide For Dogs and Cats  
56.8 mg/mL Solution

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

ANADA 200-176. Approved by FDA

**DIRECTIONS:** For I.M. or S.C. Injection.  
**Dogs:** 5 lbs. and under-0.3 mL  
6-10 lbs.-0.5 mL  
11-25 lbs.-1.0 mL  
Over 25 lbs.-0.2 mL/5 lbs. bwt. (max. 3 mL)  
**Cats:** Under 5 lbs.-0.2 mL  
5-10 lbs.-0.4 mL  
11 lbs. and over-0.6 mL maximum

Read package insert before using this drug.

Lot No.  
Exp. Date

  
3 59130 65511 7  
600066 Iss. 8-02



Bottle and Alternate  
Shipper Label

150%

NDC 59130-655-11

NET CONTENTS: 50 mL

**PraziTech™ Injection  
(praziquantel)**

Injectable Cestocide For Dogs and Cats  
56.8 mg/mL Solution

**CAUTION:** Federal law restricts this drug to use by or on  
the order of a licensed veterinarian.  
Read package insert before using this drug.

Store between 15° and 30°C (59° and 86°F)

Lot No.

Exp. Date

Manufactured by  
Phoenix Scientific, Inc. 600066  
St. Joseph, MO 64503 Iss. 8-02  
ANADA 200-176, Approved by FDA



NDC 59130-655-11

NET CONTENTS: 50 mL

**PraziTech™ Injection  
(praziquantel)**

Injectable Cestocide For Dogs and Cats  
56.8 mg/mL Solution

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

**Read package insert before using this drug.**

Store between 15° and 30°C (59° and 86°F)

Lot No.

Exp. Date

Manufactured by  
Phoenix Scientific, Inc. 600066  
St. Joseph, MO 64503 Iss. 8-02  
ANADA 200-176, Approved by FDA



Individual Chipboard  
Box Label

200%

ANADA 200-176, Approved by FDA

**PraziTech™ Injection**

(praziquantel)

Injectable Cestocide

For Dogs and Cats

56.8 mg/mL Solution

**CAUTION:**

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

**DESCRIPTION:**

PraziTech™ Injection is a clear solution containing 56.8 milligrams of praziquantel per mL which has been formulated for subcutaneous or intramuscular use in dogs and cats for removal of cestodes (tapeworms).

**INDICATIONS:**

PraziTech™ Injection is indicated for the removal of the following canine and/or feline cestodes. Dogs: *Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*. Cats: *Taenia taeniaeformis* and *Dipylidium caninum*.

**ACTION:**

PraziTech™ Injection is absorbed, metabolized in the liver and excreted via the bile into the digestive tract where its cestocidal activity is exerted. 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. It is common to see only disintegrated and partially digested pieces of tapeworms in the stool. The majority of tapeworms killed are digested and are not found in the feces.

**USE DIRECTIONS:**

PraziTech™ Injection may be administered by either the subcutaneous or intramuscular route to dogs and cats. The recommended dosage of praziquantel varies according to body weight. Smaller animals require a relatively larger dosage. The optimum dosage for each individual animal will be achieved by utilizing the following dosage schedule.

**DOGS AND PUPPIES†**

Dogs:

5 lbs. and under	0.3 mL
6-10 lbs.	0.5 mL
11-25 lbs.	1.0 mL
over 25 lbs.	0.2 mL / 5 lbs. body weight to a maximum of 3 mL

†Not intended for use in puppies less than four (4) weeks of age.

**CATS AND KITTENS††**

Cats:

Under 5 lbs.	0.2 mL
5-10 lbs.	0.4 mL
11 lbs. and over	0.6 mL maximum

††Not intended for use in kittens less than six (6) 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.

**ADMINISTRATION:**

PraziTech™ Injection may be administered by either the subcutaneous or intramuscular route to dogs and cats. The intramuscular route may be preferred in dogs due to a brief period of pain that occasionally follows subcutaneous administration.

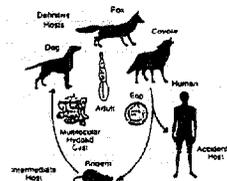
Anaphylactoid reactions were not observed in clinical trials. However, as with any drug an anaphylactoid reaction can occur with this product and should be treated symptomatically if it occurs.

**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.

**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 above.

The adult tapeworm is small (1-4mm) 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 the infected rodent, larvae within the cyst develop to 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.<sup>2,3</sup>

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 PraziTech™ Injection, following the dosing schedule aforementioned and precautions indicated below.

Additional information on the life cycle and epidemiology of this parasite is available in veterinary parasitology texts.<sup>4,5</sup>

**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 taenid 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 PraziTech™ Injection 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 PraziTech™ Injection 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.<sup>6</sup> 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 signs of clinical toxicity following either intramuscular or subcutaneous injections. No significant clinical chemistry, hematological, cholinesterase or histopathological changes occurred. Dosages of 5 times the labeled rate at 14 day intervals to kittens as young as 5 1/2 weeks did not produce signs of clinical toxicity following either intramuscular or subcutaneous injections. Symptoms of overdosage (33.8 to 40 times the labeled dosage rate) in adult dogs included vomiting, excessive salivation and depression, but no deaths. Symptoms of overdosage (10 to 20 times the labeled dosage rate) in adult cats included vomiting, depression, muscle tremors and incoordination. Deaths occurred in 5 of 8 cats treated subcutaneously and in all 8 injected intramuscularly at doses greater than 20 times the label rate.

**CONTRAINDICATIONS:**

There are no known contraindications to the use of praziquantel.

**PREGNANCY:**

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

**ADVERSE REACTION:**

Mild side effects were observed in 18 of 189 dogs (9.5%) and 8 of 85 cats (9.4%) administered praziquantel in field trials. For dogs the majority of these were described as brief pain responses following injections to larger dogs (weighing over 50 lbs). Two dogs exhibited a brief period of mild vomiting and/or drowsy or staggering gait. The eight cats exhibited either diarrhea, weakness, vomiting, salivation, sleepiness, burning on injection and/or a temporary lack of appetite. Local irritation or swelling at the site of subcutaneous injections have been reported for cats.

**How Supplied:** 10 mL vial, 50 mL vial.

Store between 15° and 30°C (59° and 86°F)

**REFERENCES:**

1. Andrews, P., Pharmacokinetic Studies with DRONCIT® in Animals Using a Biological Assay. *Veterinary Medical Review*, 2/76, pg. 154-165.
2. Hildreth, M.B., Johnson, M.D. and Kazacos K.R., 1991. A Zoonosis of Increasing Concern in the United States. *Compendium for Cont Ed*, 13(5) 727-740.
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.
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