

PRAZIQUANTEL- praziquantel injection, solution
Bimeda, Inc.

Praziquantel
(praziquantel) Injection
Injectable Cestocide for Dogs and Cats
56.8 mg/mL Solution

DESCRIPTION:

Praziquantel Injection 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:

Praziquantel Injection 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:

Praziquantel Injection is absorbed, metabolized in the liver and excreted via the bile into the digestive tract where its cestocidal activity is exerted¹. 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:

Praziquantel Injection 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.

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
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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.

10 ml: Use within 6 months of first puncture and puncture a maximum of 25 times. Any product remaining after 25 punctures or more than 6 months after initial puncture should be discarded.

50 ml: Use within 6 months of first puncture and puncture a maximum of 90 times. Any product remaining after 90 punctures or more than 6 months after initial puncture should be discarded.

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:

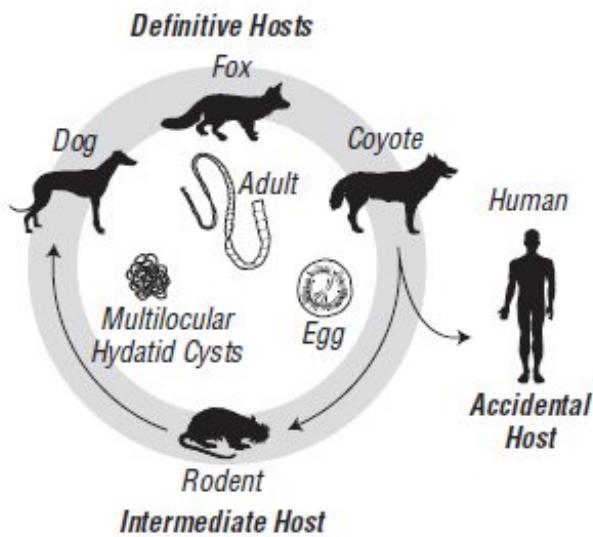
Praziquantel Injection Cestocide may be administered by either the subcutaneous or intramuscular route to dogs and cats. The intramuscular route may be preferred in dogs due to a brief period of pain that occasionally follows subcutaneous administration. Anaphylactoid reactions were not observed in clinical 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 (1-4 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 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.^{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 Injection 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.^{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 Injection 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 Praziquantel Injection 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.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 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 Injection has been tested in breeding and pregnant dogs and cats. No adverse effects were noted.

ADVERSE REACTIONS:

Mild side effects were observed in 18 of 189 dogs (9.5%) and 8 of 85 cats (9.4%) administered Praziquantel Injection 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 law restricts this drug to use by or on the order of a licensed veterinarian.

STORAGE CONDITIONS: Store at or below 25°C. Do not allow to freeze.

HOW SUPPLIED:

10 mL vial

50 mL vial

REFERENCES:

¹ Andrews P. Pharmacokinetic Studies with Praziquantel Injection in Animals Using a Biological Assay. *Veterinary Medical Review*, 2/76, pg. 154-165.

² Hildreth MB, Johnson MD and Kazacos KR. 1991. A Zoonosis of Increasing Concern in the United States. *Compendium for Cont Ed.* 13(5) 727-740.

³ Lieby PD, Carney WP and Woods CE. 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 JR and Georgi ME. 1990. *Parasitology for Veterinarians*. W.B. Saunders Co. 118-138.

⁵ Soulsby EJL. 1982. *Helminths, Arthropods and Protozoa of Domesticated Animals*. 7th Edition. Lea & Febigir. 118-138.

⁶ Craig PS and McPharson CNL. 1998. Sodium Hypochlorite as an Ovicide for *Echinococcus*. *Ann Trop Med and Parasit* 82(2) 211-213.

For customer service or to obtain product information, including Safety Data Sheet, call 1-888-524-6332. For medical emergencies or to report adverse reactions, call 1-888-524-6332.

86414937 LV1804

May, 2018

Manufactured for:

Bimeda, Inc.

Le Sueur, MN 56058

www.bimeda.com

Made in Germany



PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – 10 mL:



Praziquantel (praziquantel) Injection

INJECTABLE CESTOCIDE FOR DOGS AND CATS

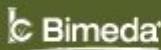
56.8 mg/mL Solution

For Removal Of *D. caninum*, *T. pisiformis*, *E. granulosus* And For Removal and Control Of *E. multilocularis* From Dogs.

For Removal of *D. caninum* And *T. taeniaeformis* From Cats.

NADA 111-607, Approved by FDA

10 mL

 Bimeda®

Praziquantel (praziquantel) Injection

INJECTABLE CESTOCIDE FOR DOGS AND CATS

56.8 mg/mL Solution

CONTAINS PER mL: Praziquantel 56.8 mg, benzyl alcohol 75 mg, chlorobutanol hydrous 5 mg in propylene glycol q.s.

NADA 111-607, Approved by FDA

10 mL



CAUTION: Federal 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

Use within 6 months of first puncture and puncture a maximum of 25 times. Any product remaining after 25 punctures or more than 6 months after initial puncture should be discarded.

Read package insert before using this drug.

Manufactured for:

Bimeda, Inc.

Le Sueur, MN 56058

www.bimeda.com

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1PRA005

B7P9

Lot:

Exp.:

Praziquantel (praziquantel) Injection

INJECTABLE CESTOCIDE FOR DOGS AND CATS

56.8 mg/mL Solution

CONTAINS PER mL: Praziquantel 56.8 mg, benzyl alcohol 75 mg, chlorobutanol hydrous 5 mg in propylene glycol q.s.

NADA 111-607, Approved by FDA

10 mL

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – 50 mL:



Praziquantel (praziquantel) Injection

INJECTABLE CESTOCIDE FOR DOGS AND CATS
56.8 mg/mL Solution

For Removal Of *D. caninum*, *T. pisiformis*, *E. granulosus* And For Removal and Control Of *E. multilocularis* From Dogs.

For Removal of *D. caninum* And *T. taeniaeformis* From Cats.

NADA 111-607, Approved by FDA

50 mL



Praziquantel

(praziquantel) Injection

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NADA 111-607, Approved by FDA



50 mL

STORAGE: Store at or below 25°C.
Do not allow to freeze.

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

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Manufactured for:
Bimeda, Inc.
Le Sueur, MN 56058
www.bimeda.com

86415070 LV1804
1PRA004

B8 PO
Lot
Exp.

Praziquantel (praziquantel) Injection

INJECTABLE CESTOCIDE FOR DOGS AND CATS

56.8 mg/mL Solution

CONTAINS PER mL: Praziquantel 56.8 mg, benzyl alcohol 75 mg, chlorobutanol hydrous 5 mg in propylene glycol q.s.

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NADA 111-607, Approved by FDA

50 mL

PRAZIQUANTEL

praziquantel injection, solution

Product Information

Product Type	PREScription ANIMAL DRUG	Item Code (Source)	NDC:61133-1400
Route of Administration	INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZIQUANTEL	56.8 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61133-1400-1	1 in 1 CARTON		
1		10 mL in 1 VIAL		
2	NDC:61133-1400-2	1 in 1 CARTON		
2		50 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA111607	04/01/2013	

Labeler - Bimeda, Inc. (060492923)

Registrant - Bayer HealthCare, LLC (152266193)

Revised: 2/2019

Bimeda, Inc.