PRAZIQUANTEL - praziquantel tablet, chewable
FELIX PHARMACEUTICALS PRIVATE LIMITED

Praziquantel Tablets
34 mg
Canine Cestocide

SPL UNCLASSIFIED SECTION

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.
Each Chewable Tablet contains 34 mg praziquantel.

DESCRIPTION

Praziquantel Tablets 34 mg Canine Cestocide 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 34 mg Canine Cestocide 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.*

CONTRAINDICATIONS

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

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 34 mg Canine Cestocide 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	½ tablet
6-10 lbs.	1 tablet
11-15 lbs.	1½ 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.**

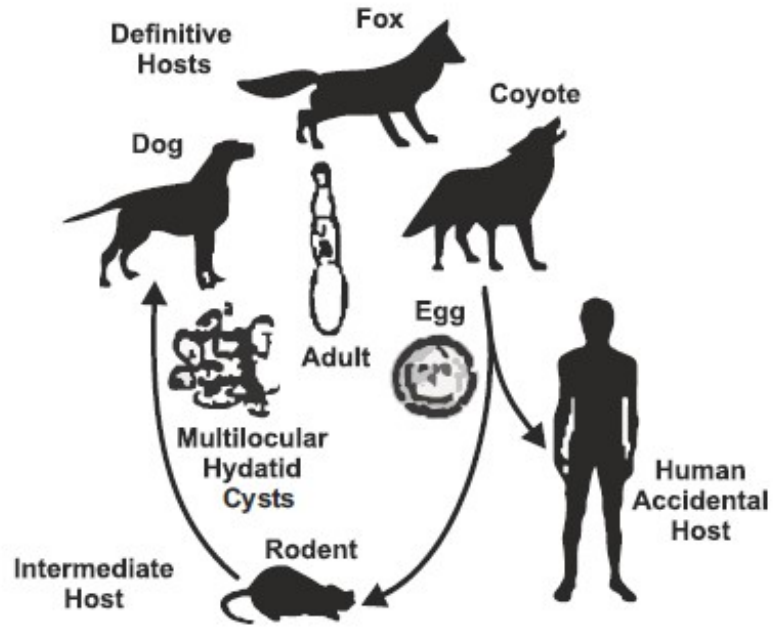
RETREATMENT

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.



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 lifecycle. 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 dosage schedule (above) and the 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 Tablets for removal of *E. multilocularis* are 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.

ANIMAL SAFETY

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 vomition, salivation, diarrhea and depression.

PREGNANCY

Praziquantel tablets have 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 34 canine cestocide. The investigators rated these as non-significant.

Contact Information: To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Felix Pharmaceuticals Private Limited at 1-833-571-1525. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

WARNING

Keep out of the reach of children. Not for human use. For customer service or to obtain product information, including Safety Data Sheet, call 1-833-571-1525.

Keep Praziquantel Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

STORAGE

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Use within 60 days of splitting.

HOW SUPPLIED

Bottle of 5, 50 and 150 scored tablets.

Each scored tablet contains 34 mg praziquantel.

NDC Number	Tablet Size	Tablets/Bottle
86101-021-21	34 mg	5 Tablets
86101-021-50	34 mg	50 Tablets
86101-021-13	34 mg	150 Tablets

REFERENCES

[1]Andrews, P. Pharmacokinetic Studies with Droncit® in Animals Using a Biological Assay. *Veterinary Medical Review* 2/76: 154-165.
[2]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.
[3]Lieby, P.O., 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 & Febigir 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.

Approved by FDA under ANADA # 200-734

Distributed by:
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Suite 100, Kansas City, Missouri 64150

Made in India

Neutral Code No. MP/DRUGS/25/90/2020

Rev. December 2024

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 86101-021-21

Praziquantel Tablets

34 mg

Canine Cestocide

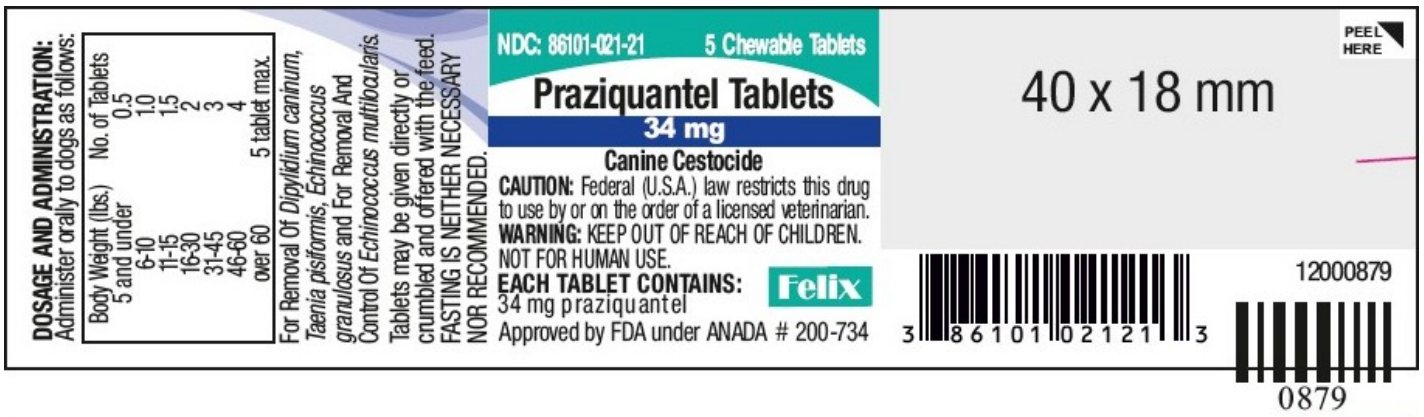
CAUTION: Federal (U.S.A) law restricts this drug to use by or on the order of a licensed veterinarian.

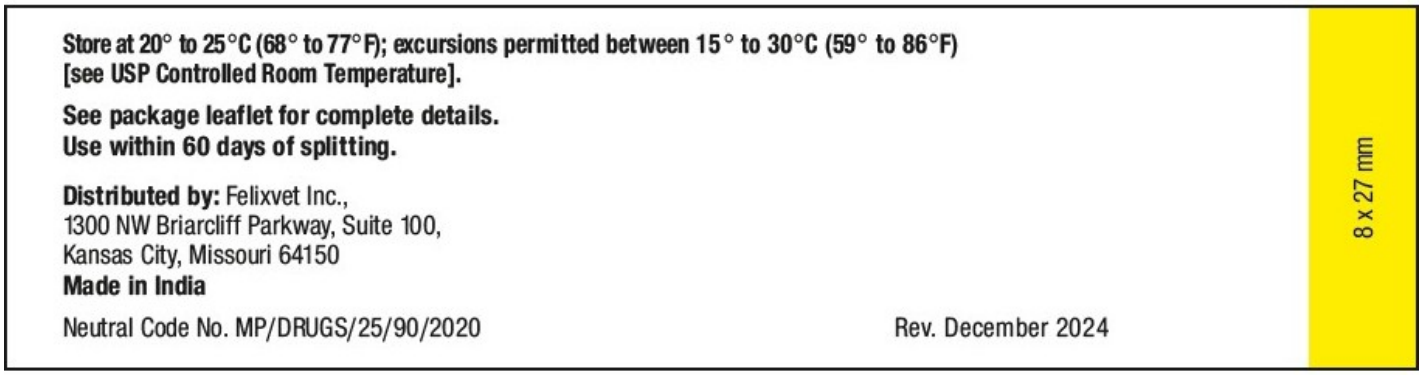
WARNING: KEEP OUT OF REACH OF CHILDREN. NOT FOR HUMAN USE.

EACH TABLET CONTAINS: 34 mg praziquantel

5 Chewable Tablets

Approved by FDA under ANADA # 200-734





PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 86101-021-13

Praziquantel Tablets

34 mg

Canine Cestocide

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EACH TABLET CONTAINS: 34 mg praziquantel

150 Chewable Tablets

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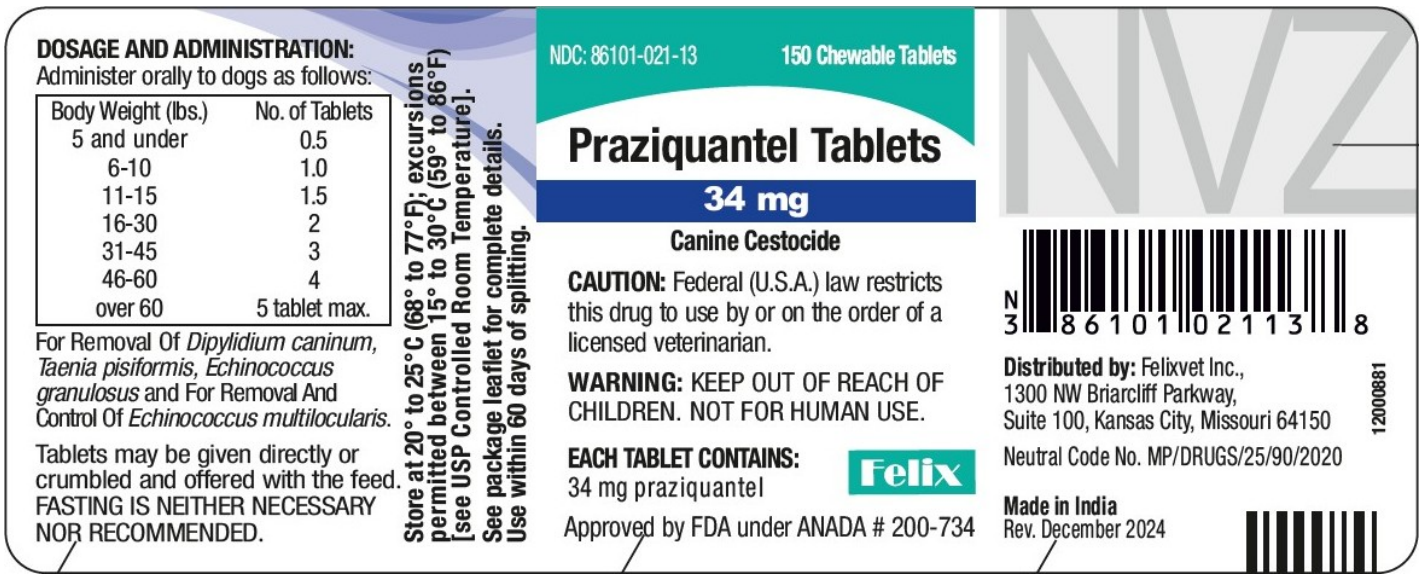

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 86101-021-50

Praziquantel Tablets

34 mg

Canine Cestocide

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EACH TABLET CONTAINS: 34 mg praziquantel

50 Chewable Tablets

Approved by FDA under ANADA # 200-734

PRAZIQUANTEL

praziquantel tablet, chewable

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:86101-021
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZIQUANTEL	34 mg

Product Characteristics			
Color	BROWN (off white to brown)	**Score**	2 pieces
Shape	ROUND (biconvex)	**Size**	11mm
Flavor	MEAT	**Imprint Code**	F;9;34
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86101-021-21	5 in 1 BOTTLE		
2	NDC:86101-021-50	50 in 1 BOTTLE		
3	NDC:86101-021-13	150 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200734	10/20/2023	

Labeler - FELIX PHARMACEUTICALS PRIVATE LIMITED (985612369)

Registrant - FELIX PHARMACEUTICALS PRIVATE LIMITED (985612369)

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