DRONCIT® R_x

Miles (formerly Haver) **Small Animal Parasiticide**

NADA No.: 111-607/111-798

Active Ingredient(s): DRONCIT® injectable cestocide is a clear solution containing:

Praziquantel ..... 56.8 mg/mL

Each canine tablet contains:

Praziquantel ..... 34 mg

Each feline tablet contains:

Praziquantel ..... 23 mg

Each feline spherical tablet contains:

Praziquantel ..... 11.5 mg

Indications: DRONCIT® (praziquantel) cestocide is indicated for the removal of *Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus* from dogs and *Dipylidium caninum* and *Taenia taeniaeformis* from cats.

Pharmacology: DRONCIT® (praziquantel) is absorbed and 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 the administration of praziquantel. In many instances, only disintegrated and partially digested pieces of tapeworms will be seen in the stool. The majority of tapeworms killed are digested and are not found in the feces.

Dosage and Administration: DRONCIT® (praziquantel) canine and feline cestocide tablets are sized for oral administration to either adult dogs or puppies and adult cats or kittens. The 34 mg praziquantel canine tablets and the 23 mg praziquantel feline tablets may be crumbled and mixed with the feed. The 11.5 mg praziquantel feline spherical tablets should be administered orally with the Haver Spherical Tablet Applicator.

The recommended dosage of praziquantel varies according to body weight. Smaller animals require a relatively larger dosage. The optimum dose for each individual animal will be achieved by utilizing the following dosage schedules:

DRONCIT® (praziquantel) injectable cestocide may be administered by either the subcutaneous or intramuscular route. The intramuscular route may be preferred in dogs due to a brief period of pain that occasionally follows subcutaneous administration.

Dogs and Puppies*	Injection
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. of body weight to a maximum of 3 mL

Cats and Kittens**	Injection
Under 5 lbs.	0.2 mL
5-10 lbs.	0.4 mL
11 lbs. and over	0.6 mL (maximum)

DRONCIT® canine (34 mg) and feline (23 mg) tablets may be administered directly per dose or crumbled and mixed with the feed. DRONCIT® feline (11.5 mg) spherical tablets should be administered orally. The recommended dose of praziquantel varies according to body weight. Smaller animals require a relatively large 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*	34 mg Tablets
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 (maximum)

Cats and Kittens**	23 mg Tablets	11.5 mg Spherical Tablets
4 lbs. and under	½ tablet	1 tablet
5-11 lbs.	1 tablet	2 tablets
Over 11 lbs.	1½ tablets	3 tablets

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

**Not intended for use in kittens of 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 gastro-intestinal tract, therefore, fasting is neither necessary nor recommended.

Retreatment: For those animals maintained on premises where re-infections are likely to occur, clients should be instructed in the steps necessary to prevent re-infection, otherwise retreatment may be necessary. This is especially true in cases of *Dipylidium caninum* infections where re-infection is almost certain to occur if fleas are not removed from the animal and its environment.

Contraindication(s): There are no known contraindications to the use of praziquantel.

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

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

Toxicology: The safety index has been derived from controlled safety evaluations, clinical trials and prior approved use in foreign countries. Dosages of five times the labeled rate at 14-day intervals to dogs as young as four weeks, and cats as young as five and one-half weeks did not produce signs of clinical toxicity following either intramuscular or subcutaneous injections or tablet administration. No significant clinical chemistry, hematological, cholinesterase or histopathological changes occurred. Symptoms of overdosage (33.8 to 40 times the labeled dosage rate) included vomition, excessive salivation, and depression, but no deaths in adult dogs. Symptoms of overdosage (10 to 20 times the labeled dosage rate) in adult cats included vomition, depression, muscle tremors and incoordination. Deaths occurred in five of eight cats treated subcutaneously and in all eight injected intramuscularly at doses greater than 20 times the label rate.

Side Effects: Pregnancy: DRONCIT® (praziquantel) has been tested in breeding and pregnant dogs and cats. No adverse effects were noted.

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. 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, vomition, 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.

Canine Tablets: 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 nonsignificant.

Feline Tablets: One instance of diarrhea and one of salivation (1.5%) were reported during the field trials in which 135 cats were administered DRONCIT® feline cestocide tablets.

References: Available upon request.

Presentation: Injectable Cestocide: 10 mL and 50 mL vials.
Canine Tablets: Bottles of 50 and 150 tablets.
Feline Tablets: Bottles of 50 and 150 tablets.
Feline Spherical Tablets: 12 packs, each pack contains a bottle of 6 tablets.

* DRONCIT is a registered trademark of the ultimate parent company of Miles Inc.

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