DRONCIT FELINE CESTOCIDE- praziquantel tablet Elanco US Inc.

Elanco™ DroncitTM (praziquantel tablets) 23 Feline Cestocide

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian. Each Tablet Contains 23 mg Praziquantel

DESCRIPTION:

Droncit (praziquantel tablets) 23 Feline Cestocide are sized for easy oral administration to either adult cats or kittens. The tablets may be crumbled and mixed with the feed.

INDICATIONS:

Droncit (praziquantel tablets) 23 Feline Cestocide are indicated for the removal of the following feline cestodes: *Dipylidium caninum* and *Taenia taeniaeformis*.

CONTRAINDICATIONS:

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

ACTION:

Droncit (praziquantel tablets) 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 killed are digested and are not found in the feces.

USE DIRECTIONS:

Droncit (praziquantel tablets) 23 Feline 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:

Cats and Kittens*

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 maintained on premises where reinfections are likely to occur, clients should be instructed in the steps necessary to prevent reinfection; otherwise, retreatment may be necessary. This is especially true in cases of *Dipylidium caninum* infections where reinfection is almost certain to occur if fleas are not removed from the animal and its environment.

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 cats as young as $5^{1}/2$ weeks did not produce clinical signs of toxicity. No significant clinical chemistry, hematological, or histopathological changes occurred. Symptoms of gross overdosage include vomition, salivation, diarrhea and depression.

PREGNANCY:

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

ADVERSE REACTIONS:

One instance of diarrhea and one of salivation (1.5%) were reported during the field trials in which 135 cats were administered Droncit (praziquantel tablets) 23 Feline Cestocide.

For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 888-545-5973.

For additional information about reporting adverse drug experiences 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.

^{*}Not intended for use in kittens less than 6 weeks of age.

STORAGE:

Store at less than or equal to 25°C (77°F)

HOW SUPPLIED:

Bottle of 50 and 150 scored tablets.

Each scored tablet contains 23 mg praziquantel.

- 50 Tablets
- -150 Tablets

REFERENCES:

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

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140 U.S.A.

Made in China

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Approved by FDA under NADA # 111-798

90207939_PA600229X Revised: March 2022

Elanco™

Principal Display Panel

DroncitTM

(praziquantel tablets)

23

Feline Cestocide

EACH TABLET CONTAINS: 23 mg praziguantel.

CAUTION: Federal (U.S.A.) law restricts this drug to use by or

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WARNING: KEEP OUT OF REACH OF CHILDREN.

50 Tablets

Manufactured for: Elanco US Inc.

Greenfield, IN 46140 U.S.A.



DroncitTM

(praziquantel tablets)

23

Feline Cestocide

EACH TABLET CONTAINS: 23 mg praziquantel.

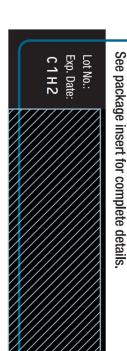
CAUTION: Federal (U.S.A.) law restricts this drug to use

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150 Tablets

Manufactured for: Elanco US Inc. Greenfield, IN 46140 U.S.A. Approved by FDA under NADA # 111-798 Made in China



STORAGE: Store at less than or equal to 25°C (77°F) NOR RECOMMENDED. Tablets may be given directly or crumbled and offered with the feed. FASTING IS NEITHER NECESSARY For removal of Dipylidium caninum and Taenia taeniaeformis Dronci (praziquantel tablets) Feline Cestocide

EACH TABLET CONTAINS: 23 mg praziquantel. **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.

150 Tablets

Manufactured for: Elanco US Inc. Greenfield, IN 461 40 U.S.A. Approved by FDA under NADA # 111-798 Made in China

DOSAGE AND ADMINISTRATION: Administer orally to cats as follows:

No. of Tablets

Body Weight (lbs.)

1.5

4 and under 5-11 over 11

90207951_YL600229A

DRONCIT FELINE CESTOCIDE

praziquantel tablet

PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:58198-0032 **Product Type Route of Administration ORAL**

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZ IQUANTEL	23 mg

Product Characteristics

Color	white (white to off white)	Score	2 pieces
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	Droncit;23
Contains			

Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	. NDC:58198-0032-1	50 in 1 BOTTLE			
2	NDC:58198-0032-2	150 in 1 BOTTLE			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA111798	12/11/1981	

Labeler - Elanco US Inc. (966985624)

Establishment			
Name	Address	ID/FEI	Business Operations
TriRx Shawnee LLC		118187894	MANUFACTURE, ANALYSIS, PACK, LABEL

Establishment			
Name	Address	ID/FEI	Business Operations
Merck KG auf Aktien		342249299	API MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
Hisun Pharmaceutical (Nantong) Co., Ltd.		421314476	API MANUFACTURE

Revised: 10/2022 Elanco US Inc.