

DRONTAL- praziquantel, pyrantel pamoate tablet
Elanco US Inc.

Elanco™
Drontal™
(praziquantel/pyrantel pamoate)
Tablets
Broad Spectrum Dewormer
For Cats And Kittens

DESCRIPTION:

Drontal (praziquantel/pyrantel pamoate) Broad Spectrum Dewormer Tablets for Cats and Kittens are scored for easy breakage. Each tablet contains 18.2 mg praziquantel and 72.6 mg pyrantel base as pyrantel pamoate.

DIRECTIONS FOR USE:

Drontal (praziquantel/pyrantel pamoate) tablets will remove Tapeworms (*Dipylidium caninum*, *Taenia taeniaeformis*), Hookworms (*Ancylostoma tubaeforme*), and Large Roundworms (*Toxocara cati*) in cats and kittens.

The presence of tapeworms is indicated by the observance of tapeworm segments passed in the cat's feces. Tapeworm segments are white, pinkish-white or yellow-white in color and are similar in size and shape to flattened grains of rice. The segments are most frequently observed lying on a freshly passed stool. Segments may also be found on the hair around the anus of the animal or on the animal's bedding. Cats become infected with tapeworms after eating fleas or small mammals (rabbits, mice) which may be infected with tapeworm larvae.

Hookworms are small whitish or reddish-brown worms less than one inch in length that live in the intestinal tract and feed on blood. Cats can become infected with hookworms by swallowing infected larvae while grooming or when larvae from the environment burrow through the skin. Cats infected with hookworms may have poor physical condition, dull haircoat, and reduced body weight and diarrhea, sometimes with the presence of dark blood.

Large roundworms are white or yellow-white strands 2-7 inches in length (similar in size and color to smooth strings of spaghetti) that may be observed in the cat's vomit or feces. Cats become infected with large roundworms by swallowing infective eggs, particularly while grooming, or by ingestion of mice that may be infected with larval stages.

Large roundworms and hookworms pass eggs in the feces of the cat that can only be observed with the aid of a microscope.

The presence of these parasites should be confirmed through identification of parasite eggs in the feces.

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasites.

Large roundworms and hookworms may be observed in the feces of the cat a day or so after the cat has been treated with Drontal Tablets. The majority of tapeworms, however, are digested and are not found in the feces after treatment.

DOSAGE AND ADMINISTRATION:

To assure proper dosage, weigh the cat prior to treatment. Select the number of whole or partial tablets needed for the cat from the following table.

<u>Body Weight*</u> <u>(lbs.)</u>	<u>Number of</u> <u>Tablets</u>
2 - 3	½
4 - 8	1
9 - 12	1 ½
13 - 16	2

*NOT FOR USE IN KITTENS LESS THAN TWO MONTHS OF AGE OR WEIGHING LESS THAN 2 LBS.

Drontal Tablets may be given directly by mouth or offered in a small amount of food. Do not withhold food from the cat prior to or after treatment.

EFFICACY:

A total of 93 cats with naturally acquired parasite infections were included in two well-controlled laboratory studies to establish the efficacy of Drontal Tablets. In addition, 85 cats and kittens of various sizes, ages and breeds were included in clinical field studies conducted at six veterinary clinics at different geographic locations throughout the United States. Data indicate 98% of the cats were completely cleared of parasite infections within 7 days of treatment. These studies demonstrated Drontal Tablets are safe and efficacious for the removal of the parasite species indicated on the label when used as directed.

SAFETY:

Cats treated with 10 times the highest recommended Drontal Tablet dosage during safety studies showed signs of vomition and salivation without other adverse effects. Eighty-three of 85 cats treated with the recommended dosages of Drontal Tablets in a clinical field study did not exhibit any drug related side effects. A temporary loss of appetite was reported for one cat and transient loose stools were observed in a second cat.

ADVERSE REACTIONS:

Post-Approval Experience: Although not all adverse reactions are reported, based on voluntary post-approval reporting, transient ataxia has been reported following the administration of Drontal Tablets for Cats and Kittens.

RETREATMENT:

Steps should be taken to prevent parasite infections, otherwise retreatment will be necessary.

Tapeworms transmitted by fleas will likely recur unless measures are taken to control fleas. Flea control procedures must include insecticide treatment of the cat's environment (i.e. bedding and resting areas) as well as direct treatment of the cat with topical solutions, dips, powders, sprays or other approved insecticides.

Roundworms and hookworms are controlled in cats by maintaining an environment free of infective eggs and larvae. Feces and soiled litter should be removed on a daily basis to prevent build-up of eggs and larvae in the environment.

Certain parasites such as tapeworms and large roundworms are transmitted to the cat after they eat infected rodents. Controlling the predatory habits of cats, i.e., catching and eating rodents, will prevent these parasite infections.

Cats maintained under conditions of constant exposure to parasite infections should have a follow-up fecal exam within 2 to 4 weeks after the first treatment.

If reinfection with tapeworms, hookworms or large roundworms occurs, treatment with Drontal Tablets may be repeated.

WARNING:

KEEP OUT OF REACH OF CHILDREN.

Consult your veterinarian before administering to sick or pregnant animals.

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.

STORAGE CONDITIONS:

Store at 20°C-25°C (68°F-77°F), excursions permitted between 15°C-30°C (59°F-86°F). Brief exposure to temperatures up to 40°C (77°F); however such exposure should be minimized.

HOW SUPPLIED:

Drontal Tablets are available in 50 tablet bottles.

- 50 tablets/bottle

Elanco™

Manufactured for:

Elanco US Inc.

Greenfield, IN 46140 U.S.A.

Approved by FDA under NADA # 141-008

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Principal Display Panel - 50 Tablet Bottle Label

Drontal™

(praziquantel/pyrantel pamoate) tablets

**Broad spectrum dewormer for
Cats and Kittens (2 to 16 lbs.)**

EACH TABLET CONTAINS: 18.2 mg praziquantel, and 72.6 mg pyrantel base as pyrantel pamoate. *Consult your veterinarian before administering to sick or pregnant animals.* Store at 20°C-25°C (68°F-77°F).

WARNING: KEEP OUT OF REACH OF CHILDREN.

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50 Tablets

Lot No.:
Exp. Date:
C1D6

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. For removal of the common parasites of cats and kittens including Tapeworms (*Dipylidium caninum*, *Taenia taeniariformis*), Hookworms (*Ancylostoma tubaeformis*) and Large Roundworms (*Toxocara cati*). **Consult package insert for further details.**

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50 Tablets

DOSAGE AND ADMINISTRATION: Administer the proper dose as specified in the following table as a single oral treatment.

Body Weight* (lbs.)	No. of Tablets
2-3	0.5
4-8	1.0
9-12	1.5
13-16	2.0

*NOT FOR USE IN KITTENS LESS THAN 2 MONTHS OF AGE OR WEIGHING LESS THAN 2 LBS.

Drontal Tablets may be given directly by mouth or offered in a small amount of food. Do not withhold food from the cat prior to or after treatment.

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DRONTAL

praziquantel, pyrantel pamoate tablet

Product Information

Product Type

OTC ANIMAL DRUG

Item Code (Source)

NDC:58198-0034

Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	PRAZQUANTEL (UNII: 6490C9U457) (PRAZQUANTEL - UNII:6490C9U457)	PRAZQUANTEL	18.2 mg	
	PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)	PYRANTEL	72.6 mg	
Product Characteristics				
Color	YELLOW (YELLOW)	Score	4 pieces	
Shape	ROUND (ROUND)	Size	10mm	
Flavor		Imprint Code	D8	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-0034-1	50 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA141008	09/29/1983		

Labeler - Elanco US Inc. (966985624)

Revised: 4/2023

Elanco US Inc.