

HEARTGARD- ivermectin tablet, chewable
Boehringer Ingelheim Animal Health USA Inc.

Heartgard®
(ivermectin)

Chewables for Cats

Caution:

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

INDICATION:

For use in cats to prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection, and for the removal and control of adult and immature hookworms (*Ancylostoma tubaeforme* and *A. braziliense*).

DOSAGE:

HEARTGARD for Cats should be administered orally at monthly intervals at the recommended minimum dose level of 24 mcg of ivermectin per kg (10.9 mcg/lb) of body weight. The recommended dosage schedule for prevention of feline heartworm disease and control of hookworm is as follows:

Cat Weight lb	HEARTGARD for Cats Chewables per Month	Ivermectin content
Up to 5 lb	1	55 mcg
5 to 15 lb	1	165 mcg

For cats over 15 lb, use the appropriate combination of chewables.
HEARTGARD for Cats is recommended for use in cats 6 weeks of age and older.

ADMINISTRATION:

Remove only one chewable at a time from the foil-backed blister card. Return the card with the remaining chewables to its box to protect the product from light. HEARTGARD for Cats can be offered to the cat by hand or may be added to a small amount of cat food. If manual dosing is required, the chewable should be broken into pieces for administration. Food should be routinely available during the day of treatment administration. If cats are fasted, or if the chewable is not broken into pieces for manual dosing, then reduced absorption may result. A relationship between reduced absorption and reduced efficacy has not been established.

Care should be taken to see that the cat consumes the complete dose. Treated animals

should be observed for a few minutes after administration to ensure that part of the dose is not lost or rejected. If it is suspected that any of the dose has been lost, redosing with a new chewable is recommended. Fragments of chewables have occasionally been observed in the feces of some cats; efficacy of the product was not adversely affected.

HEARTGARD for Cats should be given at monthly intervals when mosquitoes potentially carrying infective heartworm larvae are active. The initial dose must be given within a month (30 days) after the cat's first exposure to mosquitoes. The final dose must be given within a month (30 days) after the cat's last exposure to mosquitoes. For optimal performance, HEARTGARD for Cats must be given once a month on or about the same date. If treatment is delayed, whether by a few days or many, immediate treatment with HEARTGARD for Cats and resumption of the recommended dosing regimen will minimize the opportunity for development of adult heartworm.

It is recommended that cats should be tested for existing heartworm infection prior to starting treatment with HEARTGARD for Cats. Cats already infected with adult heartworms can be given HEARTGARD for Cats monthly to prevent further infections.

Monthly treatment with HEARTGARD® (ivermectin) for Cats also provides effective removal and control of adult and immature hookworms (*A. tubaeforme* and *A. braziliense*).

SAFETY:

In the clinical studies involving more than 3000 doses of HEARTGARD for Cats, observations reported within 24 hours of treatment included vomiting in $\leq 0.3\%$ and diarrhea in $\leq 0.2\%$ of the doses administered. There were no statistical differences between HEARTGARD for Cats and the product vehicle (control) for these observations.

A wide margin of safety was demonstrated in clinical trials at the recommended dose level in cats and kittens 6 weeks of age and older and in laboratory studies in cats with circulating microfilariae of *D. immitis*. A wide margin of safety has also been demonstrated at 3 times the recommended dose in pregnant or breeding queens and breeding toms. No adverse effects were observed in either male or female cats or their offspring in breeding studies. A 30-fold safety margin over the minimum recommended dosage was established in a single dose tolerance study. In growing kittens dosed monthly for 8 consecutive doses, one cat given 5 times the market dose vomited and a second cat in this group experienced diarrhea within 24 hours of the initial treatment. In clinical trials, many commonly used flea control products, anthelmintics, vaccines, antibiotics and steroid preparations were administered with HEARTGARD for Cats without incident.

To report suspected adverse drug events, for technical assistance, or to obtain a copy of the Safety Data Sheet (SDS), contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

Keep this and all drugs out of the reach of children. In case of ingestion by humans, clients should be advised to contact a physician immediately.

STABILITY:

Store at controlled room temperature of 68° F-77° F (20° C-25° C). Excursions between 59°F-86°F (15° C-30° C) are permitted.

HOW SUPPLIED:

HEARTGARD for Cats is available in two dosage strengths (see DOSAGE section) for cats of different weights. Each strength comes in a convenient carton of 6 chewables, packed 10 cartons per tray.

Marketed by
Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096
Made in USA

Approved by FDA under NADA # 141-078

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Rev. 08-2018

1050-2169-06

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PRINCIPAL DISPLAY PANEL - 55 mcg Tablet Blister Pack Carton

Heartgard®
(ivermectin)

**Chewables
for Cats**

**Administer once a month to prevent
heartworm disease and to remove and
control infections of hookworms in cats.**

***For
CATS
UP TO 5 lbs***

6 Chewables
Each chewable contains 55 mcg of ivermectin.

**Keep this and all drugs out
of the reach of children.**

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

Boehringer Ingelheim

Product 38055
1030-2603-05

Heartgard[®]
(ivermectin)
Chewables for Cats
6 Chewables For CATS
UP TO 5 lbs

Lot & Exp

Heartgard[®]

(ivermectin)
Chewables
for Cats

Administer once a month to prevent heartworm disease and to remove and control infections of hookworms in cats.

For
CATS
UP TO 5 lbs



6 Chewables

Each chewable contains 55 mcg of ivermectin.

Keep this and all drugs out of the reach of children.

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Boehringer
Ingelheim



For CATS
UP TO 5 lbs
6 Chewables

Heartgard[®]
(ivermectin)
Chewables for Cats

Heartgard[®]
(ivermectin)
Chewables for Cats

For CATS
UP TO 5 lbs
6 Chewables



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ENTER DATE ADMINISTERED:



Jan



Feb



Mar



Apr



May



Jun



Jul



Aug



Sep



Oct



Nov



Dec

Store at controlled room temperature of 68° F-77° F (20° C-25° C). Excursions between 59° F-86° F (15° C-30° C) are permitted.

Approved by FDA
under NADA # 141-078

Marketed by
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Animal Health USA Inc.
Duluth, GA 30096
Made in USA

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Heartgard[®]
(ivermectin)
Chewables for Cats

PRINCIPAL DISPLAY PANEL - 165 mcg Tablet Blister Pack Carton

Heartgard[®]

(ivermectin)

**Chewables
for Cats**

**Administer once a month to prevent
heartworm disease and to remove and
control infections of hookworms in cats.**

For

CATS

5 TO 15 lbs

6 Chewables

Each chewable contains 165 mcg of ivermectin.

**Keep this and all drugs out
of the reach of children.**

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

Boehringer Ingelheim





HEARTGARD

ivermectin tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-4040
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)	ivermectin	55 ug

Product Characteristics

Color	RED (red to red-brown)	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4040-01	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141078	06/01/2020	

HEARTGARD

ivermectin tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-4041
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)		ivermectin	165 ug	
Product Characteristics				
Color	RED (red to red-brown)	Score	no score	
Shape	ROUND	Size	14mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4041-01	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NADA	NADA141078		06/01/2020	

Labeler - Boehringer Ingelheim Animal Health USA Inc. (007134091)

Revised: 11/2023

Boehringer Ingelheim Animal Health USA Inc.