

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

Heartgard®
(ivermectin)

Chewables

1051-2594-03

Caution

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

INDICATION

For use in dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection.

DOSAGE

HEARTGARD® Chewables should be administered orally at monthly intervals at the recommended minimum dose level of 6.0 mcg of ivermectin per kilogram (2.72 mcg/lb) of body weight. (See ADMINISTRATION). The recommended dosage schedule for prevention of canine heartworm disease is as follows:

Dog Weight	Chewables Per Month	Ivermectin Content	Color Coding on Foil Backing and Carton
Up to 25 lb	1	68 mcg	Blue
26 to 50 lb	1	136 mcg	Green
51 to 100 lb	1	272 mcg	Brown

Give dogs over 100 lb the appropriate combination of these chewables.
HEARTGARD Chewables are recommended for use in dogs 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 the box to protect the product from light. Because most dogs find HEARTGARD Chewables palatable, the product can be offered to the dog by hand. Alternatively, it may be added to a small amount of dog food. The chewable should be administered in a manner that encourages the dog to chew, rather than to swallow without chewing. Chewables may be broken into pieces and fed to dogs that normally swallow treats whole.

Care should be taken to see that the dog consumes the complete dose, and 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 is recommended.

HEARTGARD Chewables should be given at monthly intervals during the period of the year when mosquitoes (vectors), potentially carrying infective heartworm larvae, are active. The initial dose must be given within a month (30 days) after the dog's first exposure to mosquitoes. The final dose must be given within a month (30 days) after the dog's last exposure to mosquitoes.

When replacing another heartworm preventive in a heartworm disease preventive program, the first dose of HEARTGARD must be given within a month (30 days) after the last dose of the former medication.

If the interval between doses exceeds a month (30 days), the efficacy of ivermectin can be reduced. For optimal performance, the chewable must be given once a month on or about the same day of the month. If treatment is delayed, whether by a few days or many, immediate treatment with HEARTGARD and resumption of the recommended dosing regimen minimizes the opportunity for the development of adult heartworms.

EFFICACY

HEARTGARD® (ivermectin) Chewables, given orally using the recommended dose and regimen, are effective against the tissue larval stage of *Dirofilaria immitis* for a month (30 days) after infection and, as a result, prevent the development of the adult stage.

ACCEPTABILITY

In acceptability and field trials, HEARTGARD Chewables were shown to be an acceptable oral dosage form that was consumed at the first offering by the majority of dogs.

PRECAUTIONS

All dogs should be tested for existing heartworm infection before starting treatment with HEARTGARD which is not effective against adult *D. immitis*. Infected dogs must be treated to remove adult heartworms and microfilariae prior to initiating a program with HEARTGARD.

While some microfilariae may be killed by the ivermectin in HEARTGARD at the recommended dose level, HEARTGARD is not effective for microfilariae clearance. A mild hypersensitivity-type reaction, presumably due to dead or dying microfilariae and particularly involving a transient diarrhea, has been observed in clinical trials with ivermectin after treatment of some dogs that have circulating microfilariae.

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. Physicians may contact a Poison Control Center for advice concerning cases of ingestion by humans.

Store between 68°F-77°F (20°-25°C). Excursions between 59°F-86°F (15°-30°C) are permitted. Protect product from light.

ADVERSE REACTIONS

The following adverse reactions have been reported following the use of HEARTGARD: Depression/lethargy, vomiting, anorexia, diarrhea, mydriasis, ataxia, staggering, convulsions and hypersalivation.

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 www.fda.gov/reportanimalae.

SAFETY

HEARTGARD has shown a wide margin of safety at the recommended dose level in dogs (See PRECAUTIONS for exceptions) including pregnant or breeding bitches, stud dogs and puppies aged 6 or more weeks. In clinical trials, many commonly used flea collars, dips, shampoos, anthelmintics, antibiotics, vaccines, and steroid preparations have been administered with HEARTGARD Chewables in a heartworm disease preventive program.

Studies with ivermectin indicate that certain dogs of the Collie breed are more sensitive to the effects of ivermectin administered at elevated dose levels (more than 16 times the target use level) than dogs of other breeds. At elevated doses, sensitive dogs showed adverse reactions which included mydriasis, depression, ataxia, tremors, drooling, paresis, recumbency, excitability, stupor, coma and death. HEARTGARD demonstrated no signs of toxicity at 10 times the recommended dose (60 mcg/kg) in sensitive Collies. Results of these trials support the safety of HEARTGARD products in dogs, including Collies, when used as recommended.

HOW SUPPLIED

HEARTGARD Chewables are available in three dosage strengths (See DOSAGE section) for dogs of different weights. Each strength comes in convenient cartons of 6 chewables, packed 10 cartons per tray.

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

Approved by FDA under NADA # 140-886

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Made in the USA.
December 2018

PRINCIPAL DISPLAY PANEL - 6 Tablet Carton (For DOGS UP TO 25 lbs)

Heartgard[®]
(ivermectin)

Treat once a month to prevent

heartworm disease in dogs.

***For
DOGS
UP TO 25 lbs***

6 Chewables

Each chewable contains 68 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 38174
10 30 02 20 05

Heartgard®

(ivermectin)

6 Chewables

For DOGS
UP TO 25 lbs

Lot & Exp

Heartgard®

(ivermectin)

Treat once a month to prevent heartworm disease in dogs.

For
DOGS
UP TO 25 lbs



6 Chewables

Each chewable contains 68 mcg of ivermectin.

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Boehringer
Ingelheim



For DOGS
UP TO 25 lbs

6 Chewables

Heartgard®
(ivermectin)



1030027005

ENTER DATE ADMINISTERED:



Store between 68°F-77°F (20°-25°C). Excursions between 59°F-86°F (15°-30°C) are permitted. Protect product from light.

Approved by FDA
Under IND # 146-886

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

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Heartgard®
(ivermectin)

Heartgard®
(ivermectin)

For DOGS
UP TO 25 lbs

6 Chewables

PRINCIPAL DISPLAY PANEL - 6 Tablet Carton (For DOGS 26-50 lbs)

Heartgard[®]
(ivermectin)

**Treat once a month to prevent
heartworm disease in dogs.**

**For
DOGS
26-50 lbs**

6 Chewables

Each chewable contains 136 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

100-0-271-05
Product 38175

Heartgard®

(ivermectin)

For DOGS
26-50 lbs

6 Chewables

Lot & Exp

Heartgard®

(ivermectin)

Treat once a month to prevent heartworm disease in dogs.

For
DOGS
26-50 lbs



6 Chewables



Each chewable contains 136 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

For DOGS
26-50 lbs
6 Chewables

Heartgard®
(ivermectin)



1030027105

ENTER DATE ADMINISTERED:



Store between 68°F-77°F (20°-25°C). Excursions between 59°F-86°F (15°-30°C) are permitted. Protect product from light.

Approved by FDA
under NADA # 141-086

Marketed by Boehringer
Ingelheim Animal Health USA, Inc.
P.O. Box 1000
Millsboro, DE 19966
Made in USA

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Heartgard®
(ivermectin)

For DOGS
26-50 lbs
6 Chewables



Heartgard®
(ivermectin)



PRINCIPAL DISPLAY PANEL - 6 Tablet Carton (For DOGS 51-100 lbs)

Heartgard[®]
(ivermectin)

**Treat once a month to prevent
heartworm disease in dogs.**

**For
DOGS
51-100 lbs**

6 Chewables

Each chewable contains 272 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 38176
10-30-02-72-06

Heartgard[®]
(ivermectin)

For **DOGS**
51-100 lbs

6 Chewables

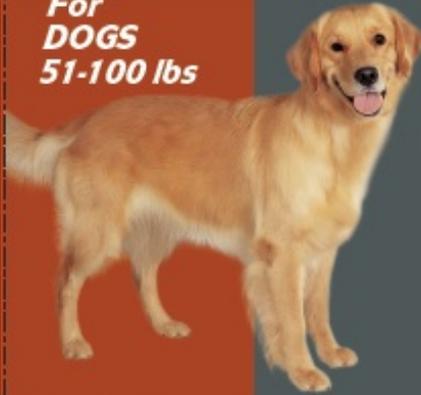
▼ Lot & Exp

Heartgard[®]

(ivermectin)

Treat once a month to prevent heartworm disease in dogs.

For **DOGS**
51-100 lbs



6 Chewables

Each chewable contains 272 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

For **DOGS**
51-100 lbs
6 Chewables

Heartgard[®]
(ivermectin)



1030027205

ENTER DATE ADMINISTERED:



Jan



Feb



Mar



Apr



May



Jun



Jul



Aug



Sep



Oct



Nov



Dec

Store between 68°F-77°F (20°-25°C). Excursions between 59°F-86°F (15°-30°C) are permitted. Protect product from light.

Heartgard[®]
(ivermectin)



HEARTGARD

ivermectin tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-4003
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)	ivermectin	68 ug

Product Characteristics

Color	RED (red to red-brown)	Score	no score
Shape	RECTANGLE	Size	20mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4003-01	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	NADA140886	06/01/2020	

HEARTGARD

ivermectin tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-4004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)	ivermectin	136 ug

Product Characteristics

Color	RED (red to red-brown)	Score	no score
Shape	RECTANGLE	Size	27mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4004-01	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	NADA140886	06/01/2020	

HEARTGARD

ivermectin tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-4005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)	ivermectin	272 ug

Product Characteristics

Color	RED (red to red-brown)	Score	no score
Shape	RECTANGLE	Size	33mm
Flavor		Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4005-01	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	NADA140886	06/01/2020	

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

Revised: 12/2023

Boehringer Ingelheim Animal Health USA Inc.