

HEARTGARD- ivermectin tablet
Boehringer Ingelheim Animal Health USA Inc.

Heartgard®
(ivermectin)
Tablets

Approved by FDA under NADA # 138-412

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. HEARTGARD® prevents heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection.

DOSAGE: HEARTGARD Tablets should be administered orally at monthly intervals at the recommended minimum dose level of 6 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	Tablets Per Month	Ivermectin Per Tablet	Color on 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 tablets.

HEARTGARD is recommended for use in dogs 6 weeks of age and older.

ADMINISTRATION: The HEARTGARD tablet should be given so that dogs swallow the whole tablet. (The tablet may be wrapped in food to encourage consumption.) 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 Tablets 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 first exposure to mosquitoes. The final dose must be given within a month (30 days) after the 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 tablet 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 Tablets, 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.

PRECAUTIONS: All dogs should be tested for existing heartworm infection before starting treatment with HEARTGARD® (ivermectin) Tablets, 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 the 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.

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 <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

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 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 is available in three dosage strengths (See DOSAGE section) for dogs of different weights. Each strength comes in a convenient carton of 6 tablets, packed 10 cartons per tray.

Store at controlled room temperature 68° - 77°F (20° - 25°C).

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

©2019 Boehringer Ingelheim Animal Health USA Inc.

All rights reserved.

Made in U.S.A.

Rev. 08-2018
1050-4383-02

®HEARTGARD and the Dog & Hand logo are registered trademarks of Boehringer Ingelheim Animal Health USA Inc.

©2019 Boehringer Ingelheim Animal Health USA Inc. All rights reserved.

Principal Display Panel - 68 mcg Tablet Carton

Heartgard®
(ivermectin)

Treat once a month to prevent heartworm disease in dogs.

For DOGS UP TO 25 lbs

6 Tablets

Each tablet contains 68 mcg 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



Principal Display Panel - 136 mcg Tablet Carton

Heartgard®
(ivermectin)

Treat once a month to prevent heartworm disease in dogs.

For DOGS 26-50 lbs

6 Tablets

Each tablet contains 136 mcg 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



Principal Display Panel - 272 mcg Tablet Carton

Heartgard®
(ivermectin)

Treat once a month to prevent heartworm disease in dogs.

For DOGS 51-100 lbs

6 Tablets

Each tablet contains 272 mcg 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

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-4023
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	WHITE	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	68;DogandHandLogo
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4023-01	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	NADA138412	04/07/2020	

HEARTGARD
ivermectin tablet

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-4024
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	WHITE	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	136;DogandHandLogo
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4024-01	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	NADA138412	04/07/2020	

HEARTGARD
ivermectin tablet

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-4025
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	WHITE	Score	no score
Shape	ROUND	Size	14mm
Flavor		Imprint Code	272;DogandHandLogo
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4025-01	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	NADA138412	04/07/2020	

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

Revised: 5/2020

Boehringer Ingelheim Animal Health USA Inc.