

**HEARTGARD FOR DOGS- ivermectin tablet**  
**Merial, Inc.**

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**Heartgard®**  
**(ivermectin)**  
**Tablets**

**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:

<b>Dog Weight</b>	<b>Tablets Per Month</b>	<b>Ivermectin Per Tablet</b>	<b>Color on Carton</b>
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.

**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).

For customer assistance, please contact Merial at 1-888-637-4251.

Marketed by  
Merial, Inc.  
Duluth, GA 30096-4640

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Made in U.S.A.

Rev. 12-2015  
1050-4383-01

**NADA 138-412, Approved by the FDA**

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**PRINCIPAL DISPLAY PANEL - 68 mcg Tablet Blister Pack 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.

**MERIAL**

# Heartgard<sup>®</sup>

(ivermectin)



For DOGS  
UP TO 25 lbs  
6 Tablets

Treat once a month to prevent heartworm disease in dogs.

For  
DOGS  
UP TO 25 lbs



# 6 Tablets

Each tablet contains 68 mcg ivermectin.



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Heartgard<sup>®</sup>  
(ivermectin)

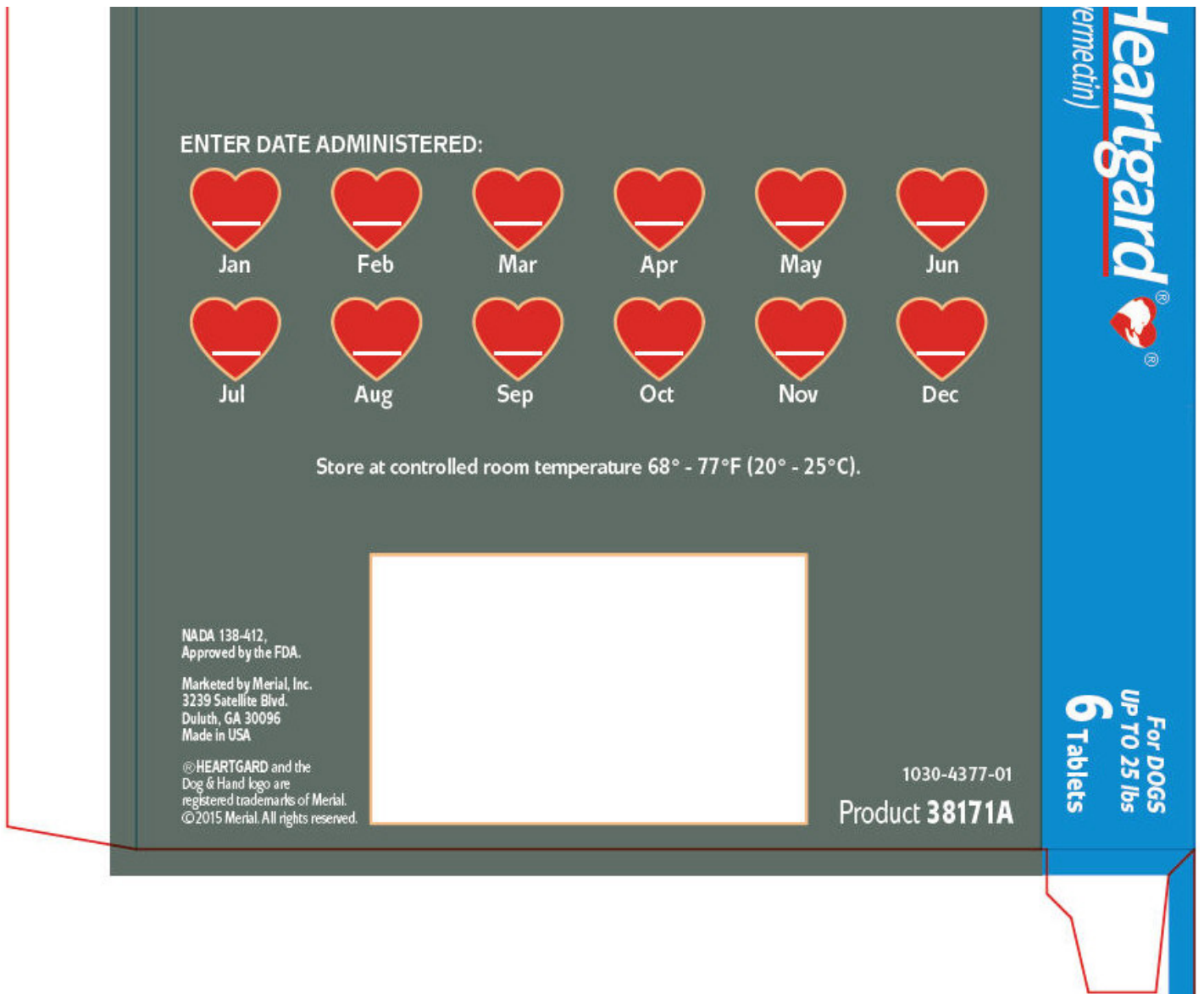
Heartgard<sup>®</sup>  
(ivermectin)



▲ Lot & Exp

For DOGS  
UP TO 25 lbs  
6 Tablets

Heartgard<sup>®</sup>  
(ivermectin)



## PRINCIPAL DISPLAY PANEL - 136 mcg Tablet Blister Pack Carton

**Heartgard<sup>®</sup>**  
(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.

**MERIAL**



# Heartgard<sup>®</sup>

(ivermectin)



For DOGS  
26-50 lbs  
6 Tablets

Treat once a month to prevent heartworm disease in dogs.

For  
DOGS  
26-50 lbs



6 Tablets

Each tablet contains 136 mcg ivermectin.



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



Heartgard<sup>®</sup>  
(ivermectin)

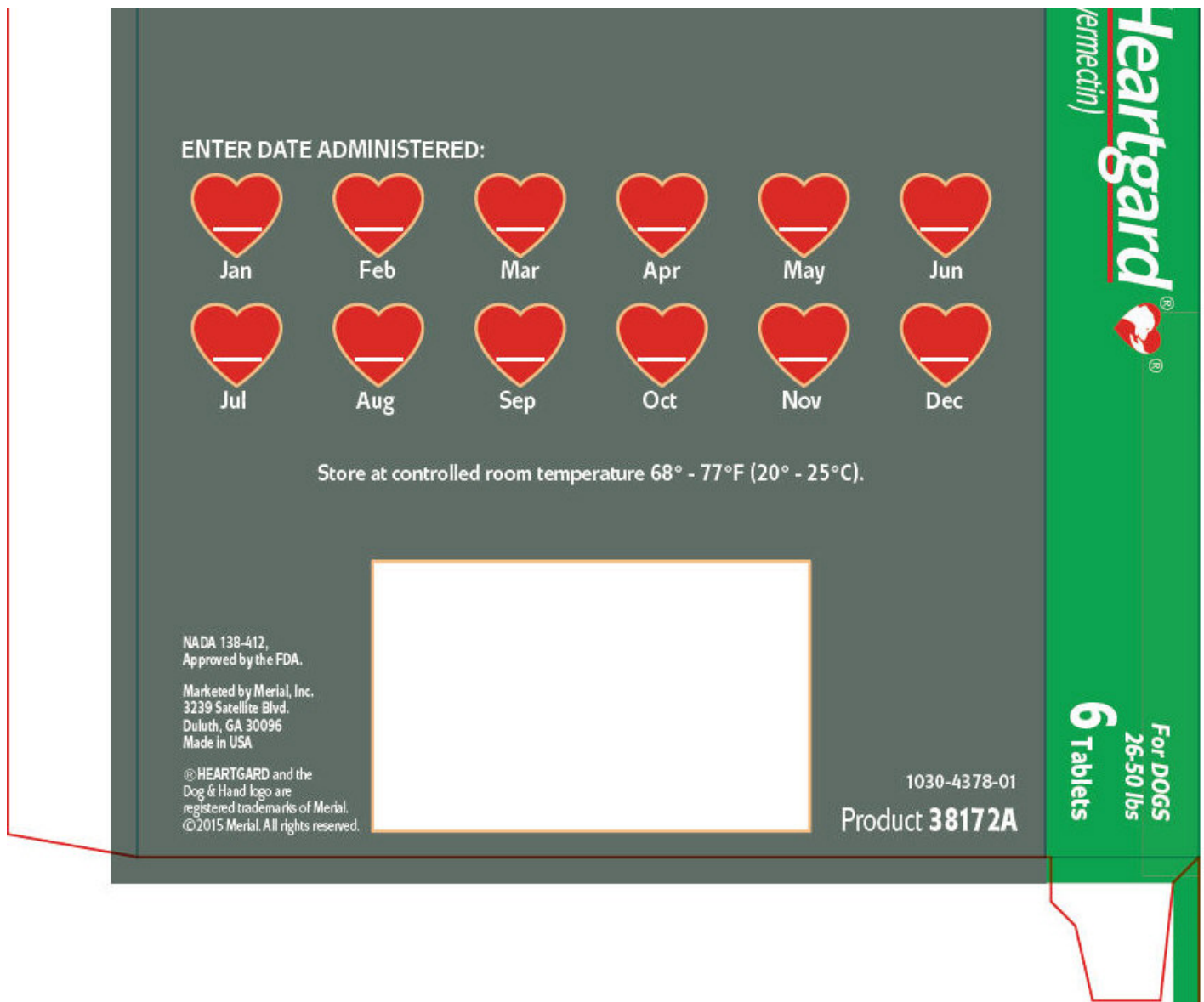
Heartgard<sup>®</sup>  
(ivermectin)



For DOGS  
26-50 lbs  
6 Tablets

▲ Lot & Exp

Heartgard<sup>®</sup>  
(ivermectin)



## PRINCIPAL DISPLAY PANEL - 272 mcg Tablet Blister Pack Carton

**Heartgard**<sup>®</sup>  
(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.

**MERIAL**





# Heartgard<sup>®</sup>

(ivermectin)



For DOGS  
51-100 lbs  
6 Tablets

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.



Heartgard<sup>®</sup>  
(ivermectin)

Heartgard<sup>®</sup>  
(ivermectin)



Heartgard<sup>®</sup>  
(ivermectin)

ENTER DATE ADMINISTERED:



Jan



Feb



Mar



Apr



May



Jun



Jul



Aug



Sep



Oct



Nov



Dec

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

NADA 138-412,  
Approved by the FDA.

Marketed by Merial, Inc.  
3239 Satellite Blvd.  
Duluth, GA 30096  
Made in USA

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1030-4379-01

Product 38173A

For DOGS  
51-100 lbs  
6 Tablets

## HEARTGARD FOR DOGS

ivermectin tablet

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:50604-4023
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm

<b>Flavor</b>		<b>Imprint Code</b>	68;DogandHandLogo	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50604-4023-1	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA138412	04/01/2014		

<b>HEARTGARD FOR DOGS</b>				
ivermectin tablet				
<b>Product Information</b>				
<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:50604-4024	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
Ingredient Name		Basis of Strength	Strength	
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)		ivermectin	136 ug	
<b>Product Characteristics</b>				
<b>Color</b>	WHITE	<b>Score</b>	no score	
<b>Shape</b>	ROUND	<b>Size</b>	11mm	
<b>Flavor</b>		<b>Imprint Code</b>	136;DogandHandLogo	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50604-4024-1	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA138412	04/01/2014		

# HEARTGARD FOR DOGS

ivermectin tablet

## Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:50604-4025
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)	ivermectin	272 ug

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	272;DogandHandLogo
<b>Contains</b>			

## Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:50604-4025-1	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NADA	NADA138412	04/01/2014	

**Labeler** - Merial, Inc. (799641006)

Revised: 11/2016

Merial, Inc.