

**TRI-HEART PLUS- ivermectin and pyrantel pamoate tablet, chewable**  
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**Intervet, Inc. a subsidiary of Merck and Company, Inc.**

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**Tri-Heart Plus (Ivermectin and Pyrantel)**

**Package Insert Top**

Tri-Heart® Plus

(ivermectin/pyrantel)

Chewable Tablets

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**INDICATIONS:** 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 and for the treatment and control of roundworms (*Toxocara canis*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*).

**DOSAGE:** Tri-Heart® Plus should be administered orally at monthly intervals at the recommended minimum dose level of 6 mcg of ivermectin per kilogram (2.72 mcg/lb) and 5 mg of pyrantel (as pamoate salt) per kg (2.27 mg/lb) of body weight. The recommended dosing schedule for prevention of canine heartworm disease and for the treatment and control of roundworms and hookworms is as follows:

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Dog Weight	Chewable Tablets per Month	Ivermectin Content	Pyrantel Content	Color Coding on Blister Card and Carton
Up to 25 lbs.	1	68 mcg	57 mg	Blue
26 to 50 lbs.	1	136 mcg	114 mg	Green
51 to 100 lbs.	1	272 mcg	227 mg	Brown

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Tri-Heart® Plus is recommended for dogs 6 weeks of age and older. For dogs over 100 lbs, use the appropriate combination of these tablets.

**ADMINISTRATION:** Remove only one chewable tablet at a time from the blister card. Because most dogs find Tri-Heart® Plus palatable, the product can be offered to the dog by hand. Alternatively, it may be added intact to a small amount of

dry food  
or placed in the back of the dog's mouth for forced swallowing.

Care should be taken 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.

Tri-Heart® Plus 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 product in a heartworm disease preventive program, the first dose of Tri-Heart® Plus must be given within a month (30 days) of the last dose of the former medication.

If the interval between doses exceeds a month (30 days), the efficacy of ivermectin can be reduced. Therefore, for optimal performance, the chewable 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 Tri-Heart® Plus and resumption of the recommended dosing regimen minimizes the opportunity for the development of adult heartworms.

Monthly treatment with Tri-Heart® Plus also provides effective treatment and control of roundworms (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*). Clients should be advised of measures to be taken to prevent reinfection with intestinal parasites.

**EFFICACY:** Tri-Heart® Plus (ivermectin/pyrantel) chewable tablets given orally using the recommended dose and regimen, are effective against the tissue larval stage of *D. immitis* for a month (30 days) after infection and, as a result, prevent the development of the adult stage. Tri-Heart® Plus chewable tablets are also effective against canine roundworms (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*).

**ACCEPTABILITY:** In acceptability trials, Tri-Heart® Plus is shown to be a palatable oral dosage form that was consumed at first offering by the majority of dogs.

**PRECAUTIONS:** All dogs should be tested for existing heartworm infection before

starting

treatment with Tri-Heart® Plus which is not effective against adult *D. immitis*. Infected dogs must be treated to remove adult heartworms and microfilariae before initiating a program with Tri-Heart® Plus.

While some microfilariae may be killed by the ivermectin in Tri-Heart® Plus at the recommended dose level, Tri-Heart® Plus 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 alone after treatment of some dogs that have circulating microfilariae.

Choking or intestinal obstruction has been reported after dosing with ivermectin/pyrantel. For dogs that normally swallow treats whole, chewables may be broken into pieces (*see Post-Approval Experience*).

**Keep this and all drugs out of the reach of children.** In case of ingestion by humans, clients should be advised to consult a physician immediately. Physicians may contact a Poison Control Center for advice concerning cases of ingestion by humans.

Keep Tri-Heart Plus in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Store at controlled room temperature of 59-86° F (15-30° C). Protect product from light.

**ADVERSE REACTIONS:** In clinical field trials with ivermectin/pyrantel, vomiting or diarrhea within 24 hours of dosing was observed (1.1% of administered doses).

**POST-APPROVAL EXPERIENCE:** The following adverse events are based on post-approval adverse drug experience reporting for ivermectin/pyrantel. Not all adverse events are reported to FDA/CVM.

It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

The following adverse events reported in dogs are listed in decreasing order of reporting frequency:

Vomiting, diarrhea, lethargy, anorexia, seizures, ataxia, muscle tremors, hypersalivation, pruritus.

In some cases, choking or intestinal obstruction has been reported after administration of ivermectin/pyrantel.

**Contact Information:** Contact Merck Animal Health at 1-800-224-5318 or [www.TriHeartPlus.com](http://www.TriHeartPlus.com).

To report suspected adverse drug experiences, contact Merck Animal Health at 1-800-224-5318.

For additional information about reporting adverse drug experiences for animal drugs,

contact FDA  
at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae> To obtain a Safety Data Sheet(s), contact  
Merck Animal Health at 1-800-224-5318 or [www.Tri-HeartPlus.com](http://www.Tri-HeartPlus.com).

**SAFETY:** 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 of 6 mcg/kg) 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. Ivermectin demonstrated no signs of toxicity at 10 times the recommended dose (60 mcg/kg) in sensitive Collies. Results of these trials and bioequivalency studies support the safety of ivermectin products in dogs, including Collies, when used as recommended.

Ivermectin/pyrantel has shown a wide margin of safety at the recommended dose level in dogs, 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 ivermectin/pyrantel in a heartworm disease preventive program.

In one trial, where some pups had parvovirus, there was a marginal reduction in efficacy against intestinal nematodes, possibly due to a change in intestinal transit time.

**HOW SUPPLIED:** Tri-Heart® Plus is available in three dosage strengths (See DOSAGE section) for dogs of different weights. Each strength comes in convenient packs of 6 chewable tablets.

Manufactured for: Intervet Inc. a subsidiary of Merck & Co. Inc., 126 E. Lincoln Avenue, Rahway, NJ 07065  
Manufactured by: Diamond Animal Health, Inc., Des Moines, IA 50327

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Approved by FDA under ANADA # 200-338

[www.TriHeartPlus.com](http://www.TriHeartPlus.com)

25 lb unit carton



**Tri-Heart Plus**  
(ivermectin/pyrantel)



**6**  
CHEWABLE TABLETS  
FOR DOGS UP TO 25 lbs



www.TriHeartPlus.com

Enter Date Administered:

Dec	Nov	Oct	Sep	Aug	Jul
Jun	May	Apr	Mar	Feb	Jan

Precaution: Chewing has been reported to have been observed in some dogs. Do not break into pieces.  
 Ivermectin and pyrantel should be administered to dogs only. Do not use in cats or other animals.  
 Keep Tri-Heart Plus in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Store at controlled room temperature of 59°-86°F (15°-28°C).  
 Protect product from light.

Manufactured for **Merck Inc.**, a subsidiary of **Merck & Co. Inc.**  
 200 Silicon Valley Road  
 Kenilworth, NJ 07033  
 Manufactured by Diamond Animal Health, Inc., Des Moines, IA 50327  
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**Tri-Heart Plus**  
(ivermectin/pyrantel)



**6**  
CHEWABLE TABLETS  
FOR DOGS UP TO 25 lbs

**6**  
CHEWABLE TABLETS  
FOR DOGS UP TO 25 lbs  
 Each chewable tablet contains 68 mcg ivermectin and 57 mg pyrantel as pamoate salt.



Administer once a month to prevent heartworm disease and to treat and control ascariid and hookworm infections in dogs.

Keep this and all drugs out of the reach of children. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.



Approved by FDA under NADA # 200-538

**Tri-Heart Plus**  
(ivermectin/pyrantel)

**6**  
CHEWABLE TABLETS  
FOR DOGS UP TO 25 lbs

26-50 lb unit carton



51-100 lb unit carton



## TRI-HEART PLUS

ivermectin and pyrantel pamoate tablet, chewable

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:0061-1346
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IVERMECTIN</b> (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	68 ug
<b>PYRANTEL PAMOATE</b> (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)	PYRANTEL	57 mg

### Product Characteristics

<b>Color</b>	brown (Light to dark brown)	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE	<b>Size</b>	14mm

<b>Flavor</b>	MEAT (Artificial beef)	<b>Imprint Code</b>	none	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0061-1346-04	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	
ANADA	ANADA200338	05/10/2013		

<b>TRIHEART PLUS</b>				
ivermectin and pyrantel pamoate tablet, chewable				
<b>Product Information</b>				
<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:0061-1339	
<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	
PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)		PYRANTEL	114 mg	
<b>Product Characteristics</b>				
<b>Color</b>	brown (Light to dark brown)	<b>Score</b>	no score	
<b>Shape</b>	RECTANGLE	<b>Size</b>	19mm	
<b>Flavor</b>	MEAT (artificial beef)	<b>Imprint Code</b>	none	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0061-1339-03	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	

ANADA	ANADA200338	05/10/2013	
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## TRIHEART PLUS

ivermectin and pyrantel pamoate tablet, chewable

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:0061-1353
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	272 ug
PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)	PYRANTEL	227 mg

### Product Characteristics

<b>Color</b>	brown (Light to dark brown)	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE	<b>Size</b>	24mm
<b>Flavor</b>	MEAT (artificial beef)	<b>Imprint Code</b>	none
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0061-1353-03	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
ANADA	ANADA200338	05/10/2013	

**Labeler** - Intervet, Inc. a subsidiary of Merck and Company, Inc. (001317601)

**Registrant** - Diamond Animal Health, Inc. (102913878)

### Establishment

Name	Address	ID/FEI	Business Operations
Diamond Animal Health, Inc.		102913878	manufacture

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Shandong Qilu King-Phar Pharmaceutical Factory		421524323	api manufacture

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Moehs Catalana SL		460021629	api manufacture

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Zhejiang Hisun Pharmaceutical Co., Ltd.		654211754	api manufacture

Revised: 1/2026

Intervet, Inc. a subsidiary of Merck and Company, Inc.