

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

Tri-Heart Plus (Ivermectin and Pyrantel)

Package Insert Top

Tri-Heart Plus

(Ivermectin and Pyrantel)

Chewable Tablets

Caution: Federal (U.S.A.) 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 ascarids (*Toxocara canis*, *Toxoscaris leonina*) and hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*).

DOSAGE: Tri-Heart® Plus ivermectin/pyrantel chewable 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) 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 ascarids and hookworms is as follows:

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

Tri-Heart® Plus ivermectin/pyrantel chewable tablets are 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 chewable tablets 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 chewable 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 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 chewable tablets 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 chewable tablets and resumption of the recommended dosing regimen minimizes the opportunity for the development of adult heartworms.

Monthly treatment with Tri-Heart® Plus chewable tablets also provides effective treatment and control of ascarids (*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 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 ascarids (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*).

ACCEPTABILITY: In acceptability trials, Tri-Heart® Plus chewable tablets were 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 chewable tablets which are 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 chewable tablets.

While some microfilariae may be killed by the ivermectin in Tri-Heart® Plus chewable tablets at the recommended dose level, Tri-Heart® Plus chewable tablets are 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.

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.

ADVERSE REACTIONS: In clinical field trials with ivermectin/pyrantel, vomiting or diarrhea within 24 hours of dosing was rarely observed (1.1% of administered doses). The following adverse reactions have been reported following the use of ivermectin at the recommended dose: depression/lethargy, vomiting, anorexia, diarrhea, mydriasis, ataxia, staggering, convulsions and hypersalivation.

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.

Store at controlled room temperature of 59-86⁰ F (15-30⁰ C). Protect product from light

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

For Technical Assistance, call Merck Animal Health: 1-800-224-5318

Manufactured for: Intervet Inc. a subsidiary of Merck and Co. Inc., Summit, NJ 07901
Manufactured by: Diamond Animal Health, Inc., a wholly owned subsidiary of Heska Corporation, Des Moines, IA 50327

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02260-1

ANADA 200-338, Approved by FDA

www.TriHeartPlus.com

25 lb unit carton

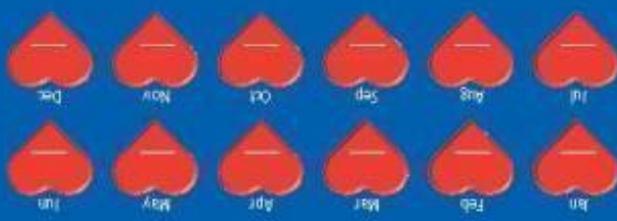


Tri-Heart Plus 
(ivermectin/pyrantel)

6
CHEWABLE TABLETS
FOR DOGS UP TO 25 lbs



Small text containing copyright information and manufacturer details for Merck Animal Health.



Enter Date Administered:

Tri-Heart Plus 
(ivermectin/pyrantel)

6
CHEWABLE TABLETS
FOR DOGS UP TO 25 lbs

Tri-Heart Plus 
(ivermectin/pyrantel)

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 ascarid and hookworm infections in dogs.

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



AVADA 100-330, approved by the FDA

Tri-Heart Plus 
(ivermectin/pyrantel)
6 CHEWABLE TABLETS FOR DOGS UP TO 25 lbs

SCHAWK P.O. 300000 SSP# 510211
Bristol, PA 03-09-05 Tri-Heart Plus
Over 25lbs



26-50 lb unit carton

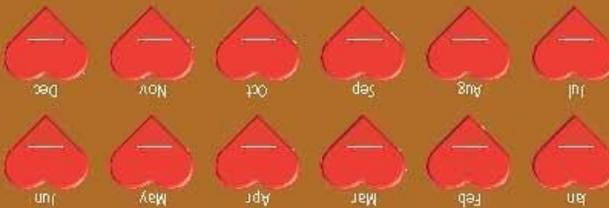
Tri-Heart Plus 
(Ivermectin/Pyrantel)

6
CHEWABLE TABLETS
FOR DOGS 51-100 lbs



www.TriHeartPlus.com

Store & control room temperature of 59-86°F (15-30°C)
 For technical assistance call: 1-800-344-5218
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 Protected product from light.
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 05252-1



Enter Date Administered:

Tri-Heart Plus 
(Ivermectin/Pyrantel)

6
CHEWABLE TABLETS
FOR DOGS 51-100 lbs

Tri-Heart Plus 
(Ivermectin/Pyrantel)

6
CHEWABLE TABLETS
FOR DOGS 51-100 lbs

Each chewable tablet contains 272 mcg ivermectin and 227 mg pyrantel as pamoate salt.

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

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.



#NADA 200-338, Approved by the FDA



6
CHEWABLE TABLETS
FOR DOGS 51-100 lbs
Tri-Heart Plus 
(Ivermectin/Pyrantel)

SCHAWK P.O. XXXXX
Safak Pant 03-09-05

SSP# 510211
Tri-Heart Plus
51-100lbs



global imaging resource network

TRI-HEART PLUS

ivermectin and pyrantel pamoate tablet, chewable

Product Information

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

Active Ingredient/Active Moiety

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

Product Characteristics

Color	brown (Light to dark brown)	Score	no score
Shape	RECTANGLE	Size	14mm
Flavor	MEAT (Artificial beef)	Imprint Code	none
Contains			

Packaging

#	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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200338	05/10/2013	

TRIHEART PLUS

ivermectin and pyrantel pamoate tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0061-1339
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Product Characteristics

Color	brown (Light to dark brown)	Score	no score
Shape	RECTANGLE	Size	19mm
Flavor	MEAT (artificial beef)	Imprint Code	none
Contains			

Packaging

#	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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200338	05/10/2013	

TRIHEART PLUS

ivermectin and pyrantel pamoate tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0061-1353
Route of Administration	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

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

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 - Heska Corp (603631326)

Establishment

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

Establishment

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

Establishment

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

Establishment

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

Revised: 8/2020

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