

HEARTSHIELD PLUS- ivermectin and pyrantel pamoate tablet, chewable
TruRX LLC

HEARTSHIELD™ plus
(ivermectin/pyrantel)
Flavored Chewables

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*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*).

DOSAGE

HEARTSHIELD PLUS™ (ivermectin/pyrantel) Flavored Chewables 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	Flavored Chewable Per Month	Ivermectin Content	Pyrantel Content
Up to 25 lbs	1	68 mcg	57 mg
26 to 50 lbs	1	136 mcg	114 mg
51 to 100 lbs	1	272 mcg	227 mg

HEARTSHIELD PLUS Flavored Chewables are recommended for dogs 6 weeks of age and older. For dogs over 100 lbs use the appropriate combination of these flavored chewables.

ADMINISTRATION

Remove only one flavored chewable at a time from the foil-backed blister card. Because most dogs find *HEARTSHIELD PLUS* Flavored Chewables palatable, the product can be offered to the dog by hand. Alternatively, it may be added intact to a small amount of dog 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.

HEARTSHIELD PLUS Flavored 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 product in a heartworm disease preventive program, the

first dose of *HEARTSHIELD* PLUS Flavored Chewables 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 flavored 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 *HEARTSHIELD* PLUS Flavored Chewables and resumption of the recommended dosing regimen minimizes the opportunity for the development of adult heartworms.

Monthly treatment with *HEARTSHIELD* PLUS Flavored Chewables 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

HEARTSHIELD PLUS Flavored Chewables, 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. *HEARTSHIELD* PLUS Flavored Chewables are also effective against canine ascarids (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*).

ACCEPTABILITY

In a trial in client-owned dogs, *HEARTSHIELD* PLUS Flavored Chewables were shown to be a palatable oral dosage form consumed at first offering by the majority of dogs.

PRECAUTIONS

All dogs should be tested for existing heartworm infection before starting treatment with *HEARTSHIELD* PLUS Flavored Chewables, which are not effective against adult *D. immitis*. Infected dogs must be treated to remove adult heartworms and microfilariae before initiating a program with *HEARTSHIELD* PLUS Flavored Chewables.

While some microfilariae may be killed by the ivermectin in *HEARTSHIELD* PLUS Flavored Chewables at the recommended dose level, *HEARTSHIELD* PLUS Flavored Chewables 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 contact a physician immediately. Physicians may contact a Poison Control Center for advice concerning cases of ingestion by humans.

Store at 20°C – 25°C (68°F – 77°F), excursions permitted between 15°C – 30°C (59°F – 86°F).

Protect product from light.

Warnings

Use product on or before its expiration date.

Discard or return unused tablets.

ADVERSE REACTIONS

In clinical 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: 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.

HOW SUPPLIED

HEARTSHIELD PLUS Flavored Chewables are available in three dosage strengths (See **DOSAGE** section) for dogs of different weights. Each strength comes in a box of 6 tablets, packed 10 boxes per display box.

ANADA 200-302, Approved by FDA.

Manufactured for: TruRx, LLC - Eagle, Idaho 83616 USA
For technical assistance or to report adverse drug reactions,
please call 1-855-631-7928.

49994-HS
06/12
302096-01

PRINCIPAL DISPLAY PANEL - up to 25 lbs Carton

VETIQ™

CONTAINS 6 FLAVORED CHEWABLES

6

**HEART
SHIELD™**

plus

(ivermectin/pyrantel)

Administer once

a month to prevent
heartworm disease

and to treat and
control ascarid

and hookworm

infections in dogs

Each flavored chewable

contains 68 mcg ivermectin and 57 mg pyrantel as pamoate salt.

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

for DOGS up to 25 lbs

Keep this and all drugs out of the reach of children.

ANADA 200-302 Approved by FDA



PRINCIPAL DISPLAY PANEL - 26 - 50 lbs Carton

VETIQ™

CONTAINS 6 FLAVORED CHEWABLES

6

**HEART
SHIELD™**

plus

(ivermectin/pyrantel)

Administer once

a month to prevent

heartworm disease

and to treat and control ascarid and hookworm infections in dogs

Each flavored chewable contains 136 mcg ivermectin and 114 mg pyrantel as pamoate salt.

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

for DOGS 26 - 50 lbs

Keep this and all drugs out of the reach of children.

ANADA 200-302 Approved by FDA



PRINCIPAL DISPLAY PANEL - 51 - 100 lbs Carton

VETIQ™

CONTAINS 6 FLAVORED CHEWABLES

6

**HEART
SHIELD™**

plus
(ivermectin/pyrantel)

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

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

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

for DOGS 51 - 100 lbs

Keep this and all drugs out of the reach of children.

ANADA 200-302 Approved by FDA



HEARTSHIELD PLUS

ivermectin and pyrantel pamoate tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:49994-105
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 (Beige speckled)	Score	no score
Shape	ROUND	Size	9mm

Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49994-105-06	6 in 1 CARTON		
1		1 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANADA	ANADA200302	08/01/2012		

HEARTSHIELD PLUS				
ivermectin and pyrantel pamoate tablet, chewable				
Product Information				
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:49994-205	
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 (Beige speckled)	Score	no score	
Shape	ROUND	Size	13mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49994-205-06	6 in 1 CARTON		
1		1 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANADA	ANADA200302	08/01/2012		

HEARTSHIELD PLUS

ivermectin and pyrantel pamoate tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:49994-305
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 (Beige speckled)	Score	no score
Shape	ROUND	Size	16mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49994-305-06	6 in 1 CARTON		
1		1 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200302	08/01/2012	

Labeler - TruRX LLC (078454338)

Establishment

Name	Address	ID/FEI	Business Operations
Virbac Corporation		829166276	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
COSMA Spa		428655732	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
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Shandong Qilu King-phar Pharmaceutical Co., Ltd.		421524323	api manufacture
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Establishment

Name	Address	ID/FEI	Business Operations
Hangzhou Minsheng Binjiang Pharmaceutical Co.,Ltd		547688780	api manufacture

Establishment

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

Revised: 11/2018

TruRX LLC