

HEART DEFENSE- ivermectin and pyrantel pamoate tablet, chewable **PetFriendly, Inc.**

Heart Defense™ (ivermectin/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: Heart Defense™ 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

Heart Defense™ 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 Heart Defense™ 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.

Heart Defense™ 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 Heart Defense™ 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 Heart Defense™ and resumption of the recommended dosing regimen minimizes the opportunity for the development of adult heartworms.

Monthly treatment with Heart Defense™ 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: Heart Defense™ (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. Heart Defense™ chewable tablets are also effective against canine ascarids (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*).

ACCEPTABILITY: In acceptability trials, Heart Defense™ was 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 Heart Defense™ which are not effective against adult *D. immitis*. Infected dogs must be treated to remove adult heartworms and microfilariae before initiating a program with Heart Defense™ chewable tablets.

While some microfilariae may be killed by the ivermectin in Heart Defense™ at the recommended dose level, Heart Defense™ 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.

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.

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 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.

To report suspected adverse drug events, for technical assistance, or to obtain a copy

of the Safety Data Sheet, contact PetFreindly, Inc. at 888-738-3911. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

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: Heart Defense™ is available in three dosage strengths (See DOSAGE section) for dogs of different weights. Each strength comes in convenient packs of 1 chewable tablet.

Manufactured by:

Diamond Animal Health, Inc.
2538 S.E. 43rd Street, Des Moines, IA 50327

Manufactured for:

PetFriendly, Inc.
8616 G Street, Omaha, NE 68127

Made in U.S.A.

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Approved by FDA under ANADA # 200–338.

Principal Display Panel - 1 Unit Blister Pack in Unit Carton for Dogs up to 25 lbs

Heart Defense™

(ivermectin/pyrantel)

68 mcg ivermectin and 57 mg pyrantel as pamoate salt

For Dogs Up to 25 lbs



Heart Defense

(ivermectin/pyrantel)

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

1 CHEWABLE TABLET

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

Keep this and all drugs out of reach of children.

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



Principal Display Panel - 1 Unit Blister Pack in Unit Carton for Dogs 26 to 50 lbs

Heart Defense™

(ivermectin/pyrantel)

136 mcg ivermectin and 114 mg pyrantel as pamoate salt

For Dogs 26 to 50 lbs



Heart Defense™

(ivermectin/pyrantel)

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

1 CHEWABLE TABLET

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

Keep this and all drugs out of reach of children.

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

For Dogs 26 to 50 lbs



Principal Display Panel - 1 Unit Blister Pack in Unit Carton for Dogs 51 to 100 lbs

Heart Defense™
(ivermectin/pyrantel)

272 mcg ivermectin and 227 mg pyrantel as pamoate salt

For Dogs 51 to 100 lbs



Heart Defense™

(ivermectin/pyrantel)

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

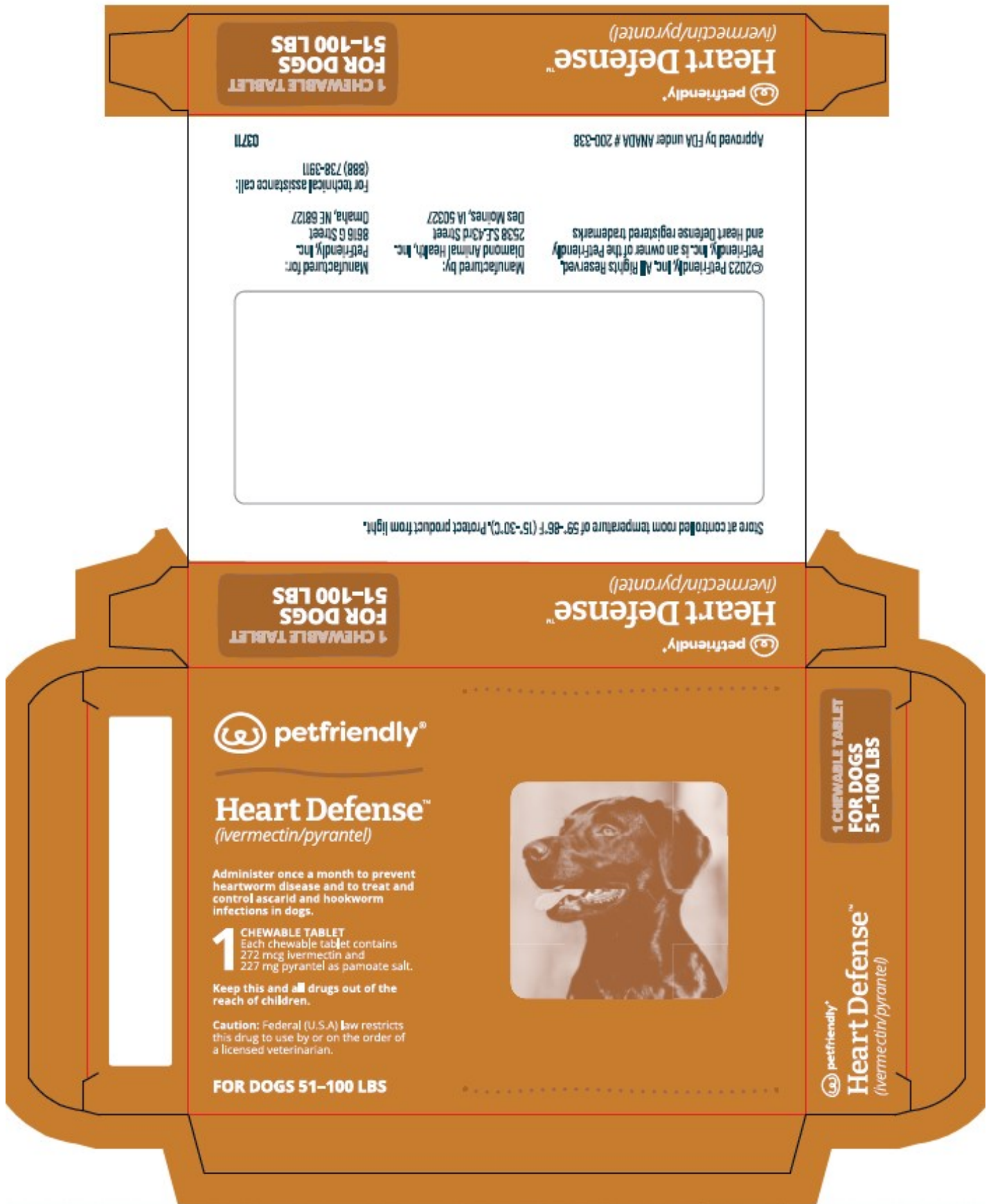
1 CHEWABLE TABLET

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

Keep this and all drugs out of reach of children.

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

For Dogs 51 to 100 lbs



petfriendly[®]

Heart Defense[™]
(ivermectin/pyrantel)

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

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

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.

FOR DOGS 51-100 LBS



1 CHEWABLE TABLET
**FOR DOGS
51-100 LBS**

petfriendly[®]
Heart Defense[™]
(ivermectin/pyrantel)

1 CHEWABLE TABLET
**FOR DOGS
51-100 LBS**

petfriendly[®]
Heart Defense[™]
(ivermectin/pyrantel)

03711

For technical assistance call:
(888) 738-3911

Manufactured for:
Pet-friendly, Inc.
8618 G Street
Omaha, NE 68127

Manufactured by:
Diamond Animal Health, Inc.
2538 S.E. 43rd Street
Des Moines, IA 50327

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and Heart Defense registered trademarks

Approved by FDA under ANADA # 200-338

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

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86172-001
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:86172-001-01	1 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	ANADA200338	06/01/2023	

HEART DEFENSE

ivermectin and pyrantel pamoate tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86172-002
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
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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:86172-002-02	1 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	ANADA200338	06/01/2023	

HEART DEFENSE

ivermectin and pyrantel pamoate tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86172-003
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:86172-003-03	1 in 1 CARTON		
1		1 in 1 BLISTER PACK		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANADA	ANADA200338	06/01/2023	

Labeler - PetFriendly, Inc. (931647916)

Registrant - Heska Corp (603631326)

Establishment

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

Revised: 11/2023

PetFriendly, Inc.