

IVERHART PLUS- ivermectin/pyrantel tablet, chewable

Virbac AH, Inc

Reference Label Set Id: 38a7a6ce-806e-46b6-8eca-5f90e294456f

Reference Label Set Id: 12b60cb1-c18c-49c4-b058-b1f6f96ee8b1

IVERHART PLUS (ivermectin/pyrantel)

See your veterinarian for more IVERHART PLUS® Flavored Chewables

**IVERHART PLUS®
(ivermectin/pyrantel)
Flavored Chewables**

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: IVERHART 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 roundworms 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

IVERHART 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 chewable at a time from the foil-backed blister card. Return the card with the remaining chewables to its box to protect the product from light. Because most dogs find IVERHART PLUS Flavored Chewables palatable, the product can be ordered to the dog by hand. Alternatively, it may be added intact to a small amount of dog food. The chewable should be administered in a manner that encourages the dog to chew, rather than to swallow without chewing. Chewables may be broken into pieces and fed to dogs that normally swallow treats whole.

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.

IVERHART 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 IVERHART 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 IVERHART PLUS Flavored Chewables and resumption of the recommended dosing regimen will minimize the opportunity for the development of adult heartworms.

Monthly treatment with IVERHART PLUS Flavored Chewables 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: IVERHART 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. IVERHART PLUS Flavored Chewables are also effective against canine roundworms (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*).

ACCEPTABILITY: In a trial in client-owned dogs, IVERHART 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 IVERHART 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 IVERHART PLUS Flavored Chewables.

While some microfilariae may be killed by the ivermectin in IVERHART PLUS Flavored Chewables at the recommended dose level, IVERHART 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.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Virbac AH, Inc at 1-800-338-3659 or us.virbac.com. 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.

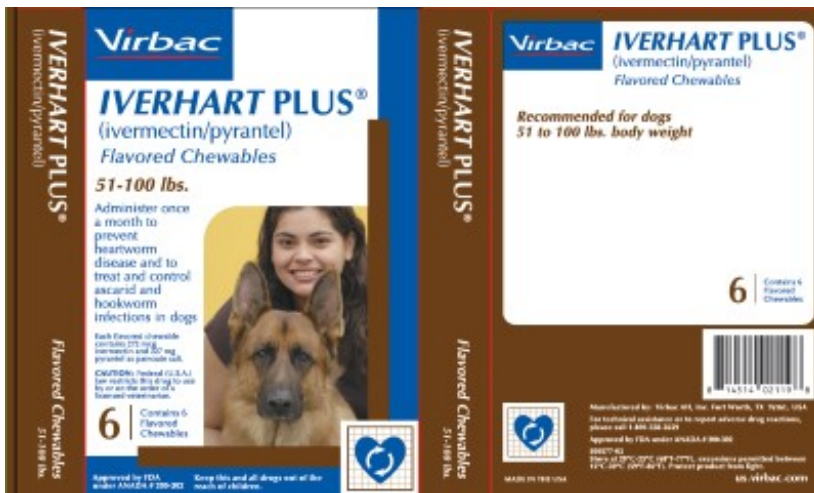
In one trial, where some pups had parvovirus, there was a marginal reduction in efficacy against intestinal nematodes, possibly due to a change in intestinal transit time.

HOW SUPPLIED: IVERHART 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.

Approved by FDA under ANADA # 200-302

Manufactured by: Virbac AH, Inc.
Fort Worth, TX 76161, USA
301732-07
03/23

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IVERHART PLUS

ivermectin/pyrantel tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-170
Route of Administration	oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	0.068 mg
PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)	PYRANTEL	57 mg

Product Characteristics

Color	brown	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-170-20	1 in 1 BOX		
1		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200302	12/03/2001	

IVERHART PLUS

ivermectin/pyrantel tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-171
Route of Administration	oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	0.136 mg
PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)	PYRANTEL	114 mg

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-171-20	1 in 1 BOX		
1		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200302	12/03/2001	

IVERHART PLUS

ivermectin/pyrantel tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-172
Route of Administration	oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	0.272 mg
PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)	PYRANTEL	227 mg

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	16mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-172-20	1 in 1 BOX		
1		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200302	12/03/2001	

Labeler - Virbac AH, Inc (131568396)

Registrant - Virbac AH, Inc (131568396)

Establishment

Name	Address	ID/FEI	Business Operations
Virbac Corporation		829166276	manufacture, analysis, label

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Cosma S.p.A		428655732	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Cipla Limited Manufacturing Division		916940208	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
SOLARA ACTIVE PHARMA SCIENCES LIMITED		676159823	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Eurofins SF Analytical Laboratories Inc		119127666	analysis

Establishment

Name	Address	ID/FEI	Business Operations
Particle Technology Labs		808076947	analysis

Establishment

Name	Address	ID/FEI	Business Operations
Alcami Carolinas Corporation		117877975	analysis