

IVERHART MAX CHEW- ivermectin/pyrantel pamoate/praziquantel tablet, chewable

Virbac AH, Inc

IVERHART MAX® Chew (ivermectin/pyrantel pamoate/praziquantel)

For oral use in dogs only.

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

Description

IVERHART MAX® Chew is a combination of three anthelmintics (ivermectin/pyrantel pamoate/praziquantel). The chews are available in four sizes in color-coded packages for oral administration to dogs according to their weight (see **Dosage and Administration**).

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*), hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*), and tapeworms (*Dipylidium caninum*, *Taenia pisiformis*).

Dosage and Administration

IVERHART MAX Chew should be administered orally at monthly intervals and the recommended minimum dose level of 6 mcg of ivermectin per kilogram (2.72 mcg/lb), 5 mg of pyrantel (as pamoate salt) per kg (2.27 mg/lb), and 5 mg of praziquantel per kg (2.27 mg/lb) of body weight, as follows:

Dosing Schedule

Dog Weight Pounds	Chew per Month	Chew Size	Ivermectin Content	Pyrantel Pamoate Content	Praziquantel Content
6.0 to 12	1	Toy	34 mcg	28.5 mg	28.5 mg
12.1 to 25	1	Small	68 mcg	57 mg	57 mg
25.1 to 50	1	Medium	136 mcg	114 mg	114 mg
50.1 to 100	1	Large	272 mcg	228 mg	228 mg

IVERHART MAX Chew is recommended for dogs 8 weeks of age or older. For dogs over 100 lbs, use the appropriate combination of these chews. Remove only one dose at a time from the packaging. Return the remaining chew(s) to their box to protect from

light. The chew can be offered to the dog by hand or added, intact, to a small amount of dog food. Care should be taken to ensure that the dog consumes the complete dose. The treated dog should be observed for a few minutes after administration to confirm that none of the dose has been lost or rejected. If it is suspected that any of the dose has been lost, redosing is recommended.

IVERHART MAX Chew 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 preventative product in a heartworm disease prevention program, the first dose of IVERHART MAX Chew must be given within a month (30 days) after the last dose of the former medication. A heartworm test should be performed prior to and 6 months after switching heartworm preventative products.

If the interval between doses exceeds a month (30 days), the effectiveness of ivermectin can be reduced. Therefore, for optimal performance, the chew 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 MAX Chew and resumption of the recommended dosing regimen will minimize the opportunity for the development of adult heartworms.

Warnings

For use in dogs only. Keep this and all drugs out of reach of children and pets. In safety studies with ivermectin/pyrantel pamoate/praziquantel tablets, testicular hypoplasia was observed in some dogs receiving 3 and 5 times the maximum recommended dose monthly for 6 months (see Animal Safety).

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.

Precautions

Use with caution in sick, debilitated, or underweight animals and dogs weighing less than 10 lbs (see Animal Safety). The safe use of this drug has not been evaluated in pregnant or lactating bitches.

All dogs should be tested for existing heartworm infection before and 6 months after starting treatment with IVERHART MAX Chew, which is not effective against adult *Dirofilaria immitis*. Infected dogs should be treated to remove adult heartworms and

microfilariae before initiating a heartworm prevention program.

While some microfilariae may be killed by the ivermectin in IVERHART MAX Chew at the recommended dose level, IVERHART MAX Chew 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.

Adverse Reactions

In a field study with IVERHART MAX Chew, self-limiting adverse reactions, including vomiting, diarrhea, lethargy, difficulty swallowing, excessive salivation, increased water consumption, and coughing were reported. Self-limiting adverse reactions, including lethargy, limpness, salivation, shaking, diarrhea, decreased appetite, licking lips, and belching were reported between 20 minutes and 72 hours following treatment in a field study with ivermectin/pyrantel pamoate/praziquantel tablets.

In field studies with ivermectin/pyrantel/praziquantel pamoate tablets, vomiting or diarrhea within 24 hours of dosing was rarely observed (1.1% of administered doses). The following adverse reactions have been reported in dogs following the use of ivermectin products: depression/lethargy, vomiting, anorexia, diarrhea, mydriasis, ataxia, staggering, convulsions, and hypersalivation.

To report suspected adverse 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 the FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

Effectiveness: Prevention of the tissue larval stage of heartworm (*Dirofilaria immitis*) and the elimination of the adult stage of hookworm (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*), roundworm (*Toxocara canis*, *Toxascaris leonina*), and tapeworm (*Dipylidium caninum*, *Taenia pisiformis*) infections in dogs was demonstrated in well-controlled laboratory studies.

Palatability: In a field study of 132 dogs, IVERHART MAX Chew was offered once monthly for 3 months. The dogs voluntarily consumed 86.3% of the doses from the owner's hand or from a bowl within 5 minutes, 13.0% accepted the dose when it was offered in food or administered by placing in the back of the dog's tongue (pilling), and 0.7% of the doses were unable to be administered.

Animal 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 dose level of 6 mcg/kg) than dogs of other breeds. At elevated doses, sensitive dogs showed more adverse reactions which included mydriasis, depression, ataxia, tremors, drooling, paresis, recumbency, excitability, stupor, coma and death. No signs of toxicity were seen at 10 times the recommended dose (27.2 mcg/lb) in sensitive Collies. Data from these studies support the safety of ivermectin products in dogs, including Collies, when used at the

label recommended dose.

Because ivermectin and praziquantel are approximately 30% more bioavailable in the IVERHART MAX Chew than in the ivermectin/pyrantel pamoate/praziquantel tablets used in the following target animal safety studies, the margin of safety is narrower than reported in these studies. The potential for adverse reactions may be greater in individual dogs administered IVERHART MAX Chew than ivermectin/pyrantel pamoate/praziquantel tablets.

In a target animal safety study using ivermectin/pyrantel pamoate/praziquantel tablets, doses were administered to 8 week old Beagle puppies at one, three, and five times the maximum recommended dose of 12.5 mcg/kg ivermectin, 10.47 mg/kg pyrantel and 10.47 mg/kg praziquantel. The dogs were treated every 30 days for 6 months. Vomiting within 6 hours of dosing and soft or watery feces within 24 hours of dosing were observed. Other observations during the study were: ano-genital swelling, lethargy, head movements, shallow, audible or difficult breathing, and salivation. One dog in the 5X group had tremors and decreased activity. All of these signs were transient. No treatment was required. Histopathology showed testicular hypoplasia in the 3X and 5X groups (**see Warnings**).

In a laboratory safety study using ivermectin/pyrantel pamoate/praziquantel tablets, 12-week-old Beagle puppies receiving 3 and 5 times the recommended dose once weekly for 13 weeks demonstrated a dose-related decrease in testicular maturation compared to controls. In this study, all treated puppies had significantly higher cholesterol levels compared to untreated controls.

In a reproductive safety study, adult males were treated at 37.5 mcg/kg ivermectin, 31.4 mg/kg pyrantel and 31.4 mg/kg praziquantel every 14 days during two full spermatogenic cycles (112 days). The quality of semen and reproductive health were not affected by treatment. Treatment related vomiting and soft feces were reported during this study.

In a study of the effectiveness of ivermectin/pyrantel pamoate/praziquantel tablets for the treatment of *Toxocara canis*, one 8.1 lb, 72-day-old puppy died 6 days after administration of the label dose. This puppy and many other puppies in the study had high worm burdens and were reported to have diarrhea, sometimes bloody, frequently before and after treatment. Dehydration and signs of anemia (pale mucous membranes) were the only abnormal gross necropsy finding observed. No definitive cause was determined. In a 90-day field study using ivermectin/pyrantel pamoate/praziquantel tablets, the most serious adverse reactions (lethargy, limpness, and salivation) were seen in dogs weighing less than 10 lbs (**see Precautions**).

Storage Information

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (59°F to 86°F). Protect product from light.

How Supplied

IVERHART MAX Chew is available in four dosage strengths (**see Dosage and Administration**) for dogs of different weights. Each strength comes in a package

of 6 chews.

Approved by FDA under NADA # 141-441

Manufactured by:
Virbac AH, Inc.
Fort Worth, TX 76137 USA
Phone: 1-800-338-3659

© 2020 Virbac Corporation. IVERHART MAX is a registered trademark of Virbac Corporation. 302143-04
10/2020

Virbac IVERHART MAX[®] Chew (ivermectin/pyrantel pamoate/praziquantel)

FOR DOGS 6-12 lbs OR OLDER

6 Chews

14514-02507-1

See package insert for complete product safety information, including contraindications, warnings, and directions. For technical assistance or to report adverse drug reactions, please call 1-800-338-3659. For complete product information, see package insert.

Manufactured by:
Virbac AH, Inc.
Fort Worth, TX 76137, USA

Approved by FDA under NADA 141-441

NET CONTENTS: Contains 6 Chews (ivermectin 1.35 mg, pyrantel pamoate 36.5 mg, and praziquantel 13.5 mg)

Prevention Against Heartworm Disease
Treatment and Control of Roundworm, Hookworm and Tapeworm Infections

Administer to dogs monthly for:

- Heartworm Disease
- Roundworm Infections
- Tapeworm Infections

6 Chews

WARNING: For use in dogs only. Keep this and all dogs out of reach of children and pets.

CAUTION: Federal (USA) law prohibits the sale of this product to the owner of a dog under 6 months of age.

Approved by FDA under NADA # 141-441

NET CONTENTS: Contains 6 Chews (ivermectin 1.35 mg, pyrantel pamoate 36.5 mg, and praziquantel 13.5 mg)



Virbac IVERHART MAX[®] Chew (ivermectin/pyrantel pamoate/praziquantel)

FOR DOGS 12.1 - 25 lbs OR OLDER

6 Chews

14514-02504-2

See package insert for complete product safety information, including contraindications, warnings, and directions. For technical assistance or to report adverse drug reactions, please call 1-800-338-3659. For complete product information, see package insert.

Manufactured by:
Virbac AH, Inc.
Fort Worth, TX 76137, USA

Approved by FDA under NADA 141-441

NET CONTENTS: Contains 6 Chews (ivermectin 1.35 mg, pyrantel pamoate 36.5 mg, and praziquantel 13.5 mg)

Prevention Against Heartworm Disease
Treatment and Control of Roundworm, Hookworm and Tapeworm Infections

Administer to dogs monthly for:

- Heartworm Disease
- Roundworm Infections
- Tapeworm Infections

6 Chews

WARNING: For use in dogs only. Keep this and all dogs out of reach of children and pets.

CAUTION: Federal (USA) law prohibits the sale of this product to the owner of a dog under 6 months of age.

Approved by FDA under NADA # 141-441

NET CONTENTS: Contains 6 Chews (ivermectin 1.35 mg, pyrantel pamoate 36.5 mg, and praziquantel 13.5 mg)



Virbac IVERHART MAX[®] Chew (ivermectin/pyrantel pamoate/praziquantel)

FOR DOGS 25.1 - 50 lbs OR OLDER

6 Chews

14514-02509-6

See package insert for complete product safety information, including contraindications, warnings, and directions. For technical assistance or to report adverse drug reactions, please call 1-800-338-3659. For complete product information, see package insert.

Manufactured by:
Virbac AH, Inc.
Fort Worth, TX 76137, USA

Approved by FDA under NADA 141-441

NET CONTENTS: Contains 6 Chews (ivermectin 1.35 mg, pyrantel pamoate 36.5 mg, and praziquantel 13.5 mg)

Prevention Against Heartworm Disease
Treatment and Control of Roundworm, Hookworm and Tapeworm Infections

Administer to dogs monthly for:

- Heartworm Disease
- Roundworm Infections
- Tapeworm Infections

6 Chews

WARNING: For use in dogs only. Keep this and all dogs out of reach of children and pets.

CAUTION: Federal (USA) law prohibits the sale of this product to the owner of a dog under 6 months of age.

Approved by FDA under NADA # 141-441

NET CONTENTS: Contains 6 Chews (ivermectin 1.35 mg, pyrantel pamoate 36.5 mg, and praziquantel 13.5 mg)





IVERHART MAX CHEW

ivermectin/pyrantel pamoate/praziquantel tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-504
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	34 ug
PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)	PYRANTEL	28.5 mg
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZIQUANTEL	28.5 mg

Product Characteristics

Color	brown	Score	no score
Shape	RECTANGLE	Size	24mm
Flavor	MEAT ((bacon))	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-504-02	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
NADA	NADA141441	03/01/2018	

IVERHART MAX CHEW

ivermectin/pyrantel pamoate/praziquantel tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-505
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
PRAZICQUANTEL (UNII: 6490C9U457) (PRAZICQUANTEL - UNII:6490C9U457)	PRAZICQUANTEL	57 mg

Product Characteristics

Color	brown	Score	no score
Shape	RECTANGLE	Size	30mm
Flavor	MEAT ((bacon))	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-505-04	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
NADA	NADA141441	03/01/2018	

IVERHART MAX CHEW

ivermectin/pyrantel pamoate/praziquantel tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-506
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
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZIQUANTEL	114 mg

Product Characteristics

Color	brown	Score	no score
Shape	RECTANGLE	Size	43mm
Flavor	MEAT ((bacon))	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-506-06	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
NADA	NADA141441	02/01/2018	

IVERHART MAX CHEW

ivermectin/pyrantel pamoate/praziquantel tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-507
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	228 mg
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZIQUANTEL	228 mg

Product Characteristics

Color	brown	Score	no score
Shape	RECTANGLE	Size	53mm
Flavor	MEAT ((bacon))	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-507-08	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
NADA	NADA141441		01/02/2017	

Labeler - Virbac AH, Inc (131568396)

Revised: 2/2024

Virbac AH, Inc