# The protection dogs need. Nothing they don't.

When heartworm prevention products and prices go to extremes, pets often lose out on getting the parasite protection they need. Keep more patients protected with proven, practically priced IVERHART® Brand Products.



# IVERHART MAX®

(ivermectin/pyrantel pamoate/praziquantel)



### 4-in-l protection against:









HEARTWORMS HOOKWORMS ROUNDWORMS TAPEWORMS

For puppies as young as 8 weeks. Toy dog dosing available.

### **IVERHART PLUS®**

(ivermectin/pyrantel)

Flavored Chewables



### 3-in-l protection against:







HEARTWORMS HOOKWORMS ROUNDWORMS

For puppies as young as 6 weeks.

### Why IVERHART® Brand Products Are Also What Clients Need



Tasty flavors make dosing easy



Practical pricing helps keep costs manageable to encourage compliance



Proven formula gives them confidence

For tools to promote the need for parasite protection in social media and more, visit vetresourcecenter.us.virbac.com.

### **Important Safety Information**

**IVERHART MAX®** Chew (ivermectin/pyrantel pamoate/praziquantel) is well tolerated. All dogs should be tested for heartworm disease before starting a preventive protocol. Following the use of IVERHART MAX® Chew, gastrointestinal and neurological side effects have been reported. For full prescribing information, contact Virbac at 1-800-338-3659 or visit us.virbac.com.

**IVERHART PLUS®** (ivermectin/pyrantel) *Flavored Chewables* is well tolerated. All dogs should be tested for heartworm disease before starting a preventive protocol. There are rare reports of digestive or neurological side effects following use of *IVERHART PLUS Flavored Chewables*. For full prescribing information, contact Virbac at 1-800-338-3659 or visit us.virbac.com.



# Keep more patients protected with proven, practically priced IVERHART Brand Products.

IVERHART MAX° Chew (Ivermectin/pyrante)   Flauored Chewables (Ivermect					
Dirofilaria immitis  Roundworms Toxocara canis Toxocara canis Toxascaris leonina  Hookworms Ancylostoma caninum Uncinaria stenocephala Ancylostoma braziliense  Tapeworms Dipylidium caninum Taenia pisiformis  Satisfaction guarantee  UP 10 1/1% SAVINGS PLR DOSE Vs. Heartgard Plus'  Satisfaction Guarantee  Satisfaction Guarantee  Satisfaction Guarantee  UP TO 32% SAVINGS PLR DOSE Vs. Heartgard Plus'  To be eligible for the guarantee, IVERHART MAX® Chew or IVERHART PLUS® Flavored Chewables must be used according to label directions, and the dog must meet certain criteria for approval. Contact Veterinary		Chew (ivermectin/pyrantel	(ivermectin/pyrantel)		
Toxoscaria canis Toxascaris leonina  Hookworms Ancylostoma caninum Uncinaria stenocephala Ancylostoma braziliense  Tapeworms Dipylidium caninum Taenia pisiformis  Satisfaction guarantee  UP TO 32% SAVINGS PER DOSE vs. Heartgard Plus  To be eligible for the guarantee, IVERHART MAX® Chew or IVERHART PLUS® Flavored Chewables must be used according to label directions, and the dog must meet certain criteria for approval. Contact Veterinary		<b>~</b>	~	~	
Ancylostoma caninum Uncinaria stenocephala Ancylostoma braziliense  Tapeworms Dipylidium caninum Taenia pisiformis  Satisfaction guarantee  UP TO 32% SAVINGS PER DOSE vs. Heartgard Plus'  Satisfaction Guaranteed  To be eligible for the guarantee, IVERHART MAX® Chew or IVERHART PLUS® Flavored Chewables must be used according to label directions, and the dog must meet certain criteria for approval. Contact Veterinary	Toxocara canis	<b>~</b>	<b>~</b>	~	
Dipylidium caninum Taenia pisiformis  Satisfaction guarantee  UP TO 14% SAVINGS PER DOSE vs. Heartgard Plus  Satisfaction Guaranteed To be eligible for the guarantee, IVERHART MAX® Chew or IVERHART PLUS® Flavored Chewables must be used according to label directions, and the dog must meet certain criteria for approval. Contact Veterinary	Ancylostoma caninum Uncinaria stenocephala	<b>~</b>	~	~	
Satisfaction Guaranteed  To be eligible for the guarantee, IVERHART MAX® Chew or IVERHART PLUS® Flavored Chewables must be used according to label directions, and the dog must meet certain criteria for approval. Contact Veterinary	Dipylidium caninum	<b>~</b>			
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PLUS® Flavored Chewables must be used according to label directions, and the dog must meet certain criteria for approval. Contact Veterinary		SAVINGS PER DOSE vs. Heortgard*Plus* n Guaranteed	SAVINGS PER DOSE vs. Heartgard® Plus¹		
	PLUS® Flavor and the dog r	ed Chewables must be must meet certain crit	e used according to lo eria for approval. Con	abel directions, tact Veterinary	
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### Important Safety Information

**IVERHART MAX® Chew (ivermectin/pyrantel pamoate/praziquantel)** is well tolerated. All dogs should be tested for heartworm disease before starting a preventive protocol. Following the use of IVERHART MAX® Chew, gastrointestinal and neurological side effects have been reported. For full prescribing information, contact Virbac at 1-800-338-3659 or visit us.virbac.com.

**IVERHART PLUS®** (ivermectin/pyrantel) Flavored Chewables is well tolerated. All dogs should be tested for heartworm disease before starting a preventive protocol. There are rare reports of digestive or neurological side effects following use of *IVERHART* PLUS Flavored Chewables. For full prescribing information, contact Virbac at 1-800-338-3659 or visit us.virbac.com.

Reference: 1. Data on file. Virbac Corporation.





(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:

Dog Weight Pounds	Chew per Month	Chew Size	lvermectin Content	Pyrantei 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 soft 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 *Dirofiliaria 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/praziouantel 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, Anyclostoma 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, tremore, 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 pupplies 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-weekold Beagle puppies receiving 3 and 5 times the recommended dose once weekly for 13 weekdemonstrated 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

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## **IVERHART 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 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:** 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 ascarids and hookworms is as follows:

Dog Weight	Flavored Chewable Per Month	Ivermectin Content	Pyrantel Content
Up to 25 lbs	1	68 mcg	57 mcg
26 to 50 lbs	1	136 mcg	114 mcg
51 to 100 lbs	1	272 mcg	227 mcg

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 flavored chewable at a time from the foil-backed blister card. Because most dogs find *IVERHART* 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.

*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 minimizes the opportunity for the development of adult heartworms.

Monthly treatment with *IVERHART* 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:** *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 ascarids (*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  $20^{\circ}\text{C}$  -  $25^{\circ}\text{C}$  ( $68^{\circ}\text{F}$  -  $77^{\circ}\text{F}$ ), excursions permitted between  $15^{\circ}\text{C}$  -  $30^{\circ}\text{C}$  ( $59^{\circ}\text{F}$  -  $86^{\circ}\text{F}$ ). 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 76137, USA

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