

PROTECT MORE DOGS THAN EVER BEFORE

with effective and affordable *IVERHART*® Brand products.

IVERHART MAX° (ivermectin/pyrantel pamoate/praziquantel) **Chewable Tablets**

prevent heartworm disease and treat and control hookworms, roundworms, and even tapeworms at a value that your clients will appreciate.



Heartworms



Hookworms



Roundworms



Tapeworms

IVERHART MAX Chewable Tablets offer:

- Proven active ingredients used by veterinarians for years
- A more cost-effective option than comparable heartworm preventives that do not control tapeworms¹
- Four convenient tablet sizes including an option for toy breeds
- A satisfaction guarantee that you and your clients can be confident in

ALSO AVAILABLE:

IVERHART PLUS® (ivermectin/pyrantel) Flavored Chewables. Offer your clients effective protection against heartworms, roundworms, and hookworms at an excellent value.

Baxter





Available in 4 tablet sizes



IVERHART PLUS® (ivermectin/pyrantel)

Flavored Chewables



IVERHART MAX®

Chewable Tablets

(ivermectin/pyrantel pamoate/praziguantel)

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

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 nisifformic)

Dosage: IVERHART MAX (ivermectin/pyrantel pamoate/praziquantel) Chewable Tablets should be administered orally at monthly intervals at 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 Lbs. | Chewable Tablet Per Month | Tablet 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 Chewable Tablets are recommended for dogs 8 weeks of age and older. For dogs over 100 lbs. use the appropriate combination of these Chewable Tablets.

Administration: Remove only one tablet at a time from the foil-backed blister card. Return the remaining tablets to their box to protect the product from light. IVERHART MAX Chewable Tablets can be offered to the dog by hand or be added intact to a small amount of dog food. Care should be taken that the dog consumes the complete dose, and the dog 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 MAX Chewable Tablets 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 prevention program, the first dose of NERHART MAX Chewable Tablets must be given within a month (30 days) of the last dose of the former medication. A heartworm test should be performed prior to switching heartworm preventive products.

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

WARNING: For use in dogs only. Keep this and all drugs out of reach of children. In safety studies, 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.

For a copy of the Material Safety Data Sheet (MSDS), or to report adverse reactions, call 1-800-338-3659.

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 hitches

All dogs should be tested for existing heartworm infection before starting treatment with IVERHART MAX Chewable Tablets, which are not effective against adult *D. 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 Chewable Tablets at the recommended dose level, IVERHART MAX Chewable Tablets 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.

Adverse Reactions: 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 IVERHART MAX Chewable Tablets.

In clinical field trials with ivermectin/pyrantel pamoate, 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.

Effectiveness: IVERHART MAX 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. IVERHART MAX Chewable Tablets are also effective against canine roundworms (*T. canis, T. leonina*), hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*), and tapeworms (*T. pisiformis*, *D. caninum*).

A total of 61 dogs and puppies with naturally acquired or experimental parasite infections treated with IVERHART MAX Chewable Tablets were enrolled in 7 well-controlled laboratory studies to establish effectiveness. These studies included dogs of various sizes, ages and breeds. Data from these studies demonstrated IVERHART MAX Chewable Tablets are safe and effective for the removal of the parasite species indicated on the label when used as directed.

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 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. No signs of toxicity were seen at 10 times the recommended dose (27.2 mcg/lb) in sensitive Collies. Results of these studies and bioequivalence studies support the safety of ivermectin products in dogs, including Collies, when used as recommended by the label.

In a target animal safety study, IVERHART MAX Chewable Tablets 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: anogenital swelling, lethargy, head movements, shallow, audible or difficult breathing, and salivation. One dog in the 5X group had tremors and decreased activity. All these signs were transient. No treatment was required. Pathology showed testicular hypoplasia in the 3 and 5X groups (see Warnings).

In a laboratory safety study, 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 IVERHART MAX Chewable Tablets for treatment of *T. canis*, one 8.1 lb, 72-day-old puppy died 6 days after administration of IVERHART MAX Chewable Tablets at the label dose. This puppy and many of the other puppies in the study had high worm burdens and were reported to have diarrhea, sometimes bloody, frequently before and after treatment with IVERHART MAX Chewable Tablets or the placebo. Dehydration and signs of anemia (pale mucous membranes) were the only abnormal gross necropsy findings observed. No definitive cause of death was determined. In a 90-day field study, the most serious ADEs (lethargy, limpness, and salivation) were seen in dogs weighing less than 10 lbs (see Precautings)

Storage Information: 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.

How Supplied: IVERHART MAX Chewable Tablets are available in four dosage strengths (see Dosage section) for dogs of different weights. Each strength comes in a box of 6 chewable tablets, packed 10 boxes per display box.

NADA 141-257, Approved by FDA.

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

IVERHART MAX is a registered trademark of Virbac Corporation.

09/11 301733-05

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 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 assarids 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 flavored chewable at a time from the foil-backed blister card. Because most dogs find INERHART 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 NERHART 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 INERHART 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 \(\frac{VERHART}{PLUS}\) Flavored Chewables, which are not effective against adult \(D.\) immits. Infected dogs must be treated to remove adult heartworms and microfilariae before initiating a program with \(\frac{VERHART}{VENS}\) 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.

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, anthelminitics, 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.

ANADA 200-302, Approved by FDA.

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

For technical assistance or to report adverse drug reactions, please call 1-800-338-3659.

IVERHART PLUS is a registered trademark of Virbac Corporation in the US.

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Broad-spectrum coverage

AT A BETTER VALUE.²



IVERHART MAX® (ivermectin/pyrantel pamoate/praziquantel) Chewable Tablets have more to offer your patients than HEARTGARD® Plus (ivermectin/pyrantel) Chewables.

| See the difference for yourself! | | | | | | |
|--|-----------------------------------|---|------------------------------|--|--|--|
| | IVERHART MAX® Chewable Tablets | IVERHART PLUS® (ivermectin/pyrantel) Flavored Chewables | HEARTGARD® Plus Chewables | | | |
| Heartworm Dirofilaria immitis | | | 0 | | | |
| Roundworms Toxocara canis Toxascaris leonina | • | • | 0 | | | |
| Hookworms Ancylostoma caninum Uncinaria stenocephala Ancylostoma braziliense | • | | 0 | | | |
| Tapeworms Dipylidium caninum Taenia pisiformis | • | | | | | |
| Satisfaction guarantee | • | • | 0 | | | |
| Toy dog dosing (6.0 lbs – 12 lbs) | • | | | | | |



DON'T LET ANOTHER DOG GO UNPROTECTED.

To order, talk to your distributor or Virbac representative, or call 800-338-3659.

All dogs should be tested for heartworm infection before starting a preventive program with IVERHART MAX Chewable Tablets. Use with caution in sick, debilitated, or underweight animals and dogs weighing less than 10 lbs. For oral use in dogs only. The safe use of this drug has not been evaluated in pregnant or lactating bitches. 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. See enclosed product insert for additional details.

All dogs should be tested for heartworm infection before starting a preventive program with *IVERHART* PLUS Flavored Chewables. In clinical trials with ivermectin/pyrantel, vomiting or diarrhea within 24 hours of dosing was rarely observed (1.1% of administered doses). For oral use in dogs only. The following adverse reactions have been reported following the use of ivermectin: depression/lethargy, vomiting, anorexia, diarrhea, mydriasis, ataxia, staggering, convulsions, and hypersalivation.

See enclosed product insert for additional details.

Passionate about animal health

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Please Contact Us At:

References: 1. Brakke Consulting, Inc



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