

Heartgard® Plus

(ivermectin/pyrantel)

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: HEARTGARD® Plus (ivermectin/pyrantel) 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 | Chewables Per Month | Ivermectin Content | Pyrantel Content | Color Coding On Foil Backing and Carton |
|--------------|---------------------|--------------------|------------------|---|
| Up to 25 lb | 1 | 68 mcg | 57 mg | Blue |
| 26 to 50 lb | 1 | 136 mcg | 114 mg | Green |
| 51 to 100 lb | 1 | 272 mcg | 227 mg | Brown |

HEARTGARD Plus is recommended for dogs 6 weeks of age and older. For dogs over 100 lb use the appropriate combination of these 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 HEARTGARD Plus palatable, the product can be offered 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.

HEARTGARD Plus 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 HEARTGARD Plus 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 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 HEARTGARD Plus and resumption of the recommended dosing regimen will minimize the opportunity for the development of adult heartworms.

Monthly treatment with HEARTGARD Plus 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: HEARTGARD Plus 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. HEARTGARD Plus Chewables are also effective against canine ascarids (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*).

ACCEPTABILITY: In acceptability and field trials, HEARTGARD Plus was shown to be an acceptable 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 HEARTGARD Plus which is not effective against adult *D. immitis*. Infected dogs must be treated to remove adult heartworms and microfilariae before initiating a program with HEARTGARD Plus.

While some microfilariae may be killed by the ivermectin in HEARTGARD Plus at the recommended dose level, HEARTGARD Plus 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 contact a physician immediately. Physicians may contact a Poison Control Center for advice concerning cases of ingestion by humans.

Store between 68°F - 77°F (20°C - 25°C). Excursions between 59°F - 86°F (15°C - 30°C) are permitted. Protect product from light.

ADVERSE REACTIONS: In clinical field trials with HEARTGARD Plus, 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 HEARTGARD: 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 Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

SAFETY: HEARTGARD Plus has been shown to be bioequivalent to HEARTGARD, with respect to the bioavailability of ivermectin. The dose regimens of HEARTGARD Plus and HEARTGARD are the same with regard to ivermectin (6 mcg/kg). 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) 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. HEARTGARD 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 HEARTGARD products in dogs, including Collies, when used as recommended.

HEARTGARD Plus 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 HEARTGARD Plus in a heartworm disease prevention 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: HEARTGARD Plus is available in three dosage strengths (See DOSAGE section) for dogs of different weights. Each strength comes in convenient cartons of 6 and 12 chewables.

Marketed by
Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096

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THE HEARTGARD® PLUS SATISFACTION GUARANTEE¹

Heartgard® Plus
(ivermectin/pyrantel)



TERMS AND CONDITIONS

* The HEARTGARD Plus Satisfaction Guarantee will be honored at Level 1 when 12 doses are administered consecutively in the previous 12 months.

** Dogs housed in intensified population facilities of 6 dogs or more will be covered under this guarantee for heartworms but not for intestinal parasites.

† All claims must be initiated within 9 months of the incident in question. After 9 months, the claim will become null and void.

†† Reimbursement is based on a set fee schedule and may not equal the amount charged to the client by the veterinary clinic.

¹ Satisfaction Guarantee void where prohibited by law. Payment obligation by Boehringer Ingelheim shall be limited solely to that which is represented herein. Any and all other costs are expressly excluded.

² Data on file at Boehringer Ingelheim.

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⁴ Heartworm Basics. American Heartworm Society website. <https://www.heartwormsociety.org/pet-owner-resources/heartworm-basics>. Accessed February 25, 2019.

⁵ Proof of prescription and purchase required.

⁶ Dogs starting on HEARTGARD Plus Chewables

- between 6 weeks and 4 months of age: covered immediately for protection against heartworms
 - between 4 and 6 months of age: covered following a negative antigen test 6 months after first dose
 - 6 months of age and older: covered if antigen tests performed prior to first dose and 6 months following first dose prove negative, and the dog was not previously positive for heartworms.
 - 6 months of age or older when switching from another brand of heartworm preventive to HEARTGARD Plus: covered if antigen tests performed within 2 weeks prior to the first dose of HEARTGARD Plus and 6 months following the first dose of HEARTGARD Plus prove negative, and the dog was not previously positive for heartworms.
- Thereafter, antigen test must be performed annually.

⁷ Product will be replaced with HEARTGARD (ivermectin) tablets.



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THE TRUSTED BRAND THAT IS #1 VET RECOMMENDED²



Why Choose HEARTGARD Plus?

- Highly effective prevention of heartworm disease
- Reliable treatment and control of hookworms and roundworms
- The palatability of HEARTGARD Plus Real-Beef Chewables for dogs



Trusted for 30+ Years and 2 Billion+ Doses.³

HEARTGARD Plus is proven safe and approved for use in:

- Puppies as young as 6 weeks and any weight
- Pregnant and lactating bitches, studs
- All breeds, including Collies



The American Heartworm Society recommends all dogs receive year-round heartworm preventives - even in low endemic areas.⁴

- In order to prevent heartworm disease, one dose of a monthly heartworm preventive must be administered at 30-day intervals, about the same day every month.



To support your efforts to prevent heartworm disease, we are proud to offer the HEARTGARD Plus Satisfaction Guarantee.

- Subject to the eligibility criteria and terms set forth on the following page.
- The HEARTGARD Plus Satisfaction Guarantee is an exclusive benefit for HEARTGARD Plus purchased from a veterinary clinic or with a written prescription via a valid veterinarian-client-patient relationship.



IMPORTANT SAFETY INFORMATION:

HEARTGARD® (ivermectin) and HEARTGARD® Plus (ivermectin/pyrantel) are well tolerated. All dogs should be tested for heartworm infection before starting a preventive program. Following the use of HEARTGARD and HEARTGARD Plus, digestive and neurological side effects have rarely been reported. For more information visit www.HEARTGARD.com.

| | HEARTWORMS | HOOKWORMS & ROUNDWORMS | PALATABILITY |
|---------------------------|--|---|---|
| | Subject to the following eligibility criteria and compensation limits, [†] we guarantee that consumers will be satisfied with HEARTGARD® Plus (ivermectin/pyrantel), provided the product has been purchased from a veterinary clinic or with a written prescription via a valid veterinarian-client-patient relationship. ⁵ | | |
| Eligibility | <p>Level 1: Dogs infected with heartworms after 12 months of continuous dosing in the prior 12 months*</p> <p>DOGS STARTING ON HEARTGARD Plus⁶:</p> <ul style="list-style-type: none"> • Between 6 weeks and 4 months of age get immediate coverage • Between 4 months and 6 months of age will be covered following a negative antigen test six months after the first dose is administered. • More than 6 months of age will be covered if two negative antigen tests are obtained; one prior to the first dose and one six months after the first dose is administered, and the dog was not previously positive for heartworms. <p>Level 2: Dogs infected with heartworms after a minimum of 9 months of continuous use of HEARTGARD Plus in the prior 12 months and/or insufficient negative antigen testing record.</p> | Dogs that received a dose of HEARTGARD Plus infected with roundworms or hookworms within 31 days of administration of the dose. | Dogs that do not accept HEARTGARD Plus Chewables |
| Qualifying Positive Tests | Two positive antigen tests, performed on samples from two separate blood collections and using two different antigen tests | Identification of parasite eggs by fecal flotation in clinic | |
| Compensation | <p>Level 1: \$500 for veterinary services</p> <p>Levels 1 & 2: Complimentary: Boehringer Ingelheim's adulticide product and a one-year supply of HEARTGARD Plus</p> | Reimbursement for the cost of the positive fecal exam and the cost of treatment based on the dog's weight ^{**} . ^{††} | Product credit or replacement HEARTGARD® (ivermectin) Tablets. ⁷ |

For more information, please contact 888-637-4251

