

Heartgard® (ivermectin/pyrantel) Plus

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.

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Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096
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Heartgard®

(ivermectin)

CHEWABLES

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

INDICATION: 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.

DOSAGE: HEARTGARD® Chewables should be administered orally at monthly intervals at the recommended minimum dose level of 6.0 mcg of ivermectin per kilogram (2.72 mcg/lb) of body weight. (See ADMINISTRATION). The recommended dosage schedule for prevention of canine heartworm disease is as follows:

Dog Weight	Chewables Per Month	Ivermectin Content	Color Coding On Foil Backing and Carton
Up to 25 lb	1	68 mcg	Blue
26 to 50 lb	1	136 mcg	Green
51 to 100 lb	1	272 mcg	Brown

Give dogs over 100 lbs the appropriate combination of these chewables.

HEARTGARD Chewables are recommended for use in dogs 6 weeks of age and older.

ADMINISTRATION: Remove only one chewable at a time from the foil-backed blister card. Return the card with the remaining chewables to the box to protect the product from light. Because most dogs find HEARTGARD Chewables palatable, the product can be offered to the dog by hand. Alternatively, it may be added 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 to see 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 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 in a heartworm disease preventive program, the first dose of HEARTGARD must be given within a month (30 days) after the last dose of the former medication.

If the interval between doses exceeds a month (30 days), the efficacy of ivermectin can be reduced. 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 and resumption of the recommended dosing regimen minimizes the opportunity for the development of adult heartworms.

EFFICACY: HEARTGARD Chewables, given orally using the recommended dose and regimen, are effective against the tissue larval stage of *Dirofilaria immitis* for a month (30 days) after infection and, as a result, prevent the development of the adult stage.

ACCEPTABILITY: In acceptability and field trials, HEARTGARD Chewables were shown to be an acceptable oral dosage form that was consumed at the first offering by the majority of dogs.

PRECAUTIONS: All dogs should be tested for existing heartworm infection before starting treatment with HEARTGARD® (ivermectin), which is not effective against adult *D. immitis*. Infected dogs must be treated to remove adult heartworms and microfilariae prior to initiating a program with HEARTGARD.

While some microfilariae may be killed by the ivermectin in HEARTGARD at the recommended dose level, HEARTGARD 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 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: 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 www.fda.gov/reportanimalae.

SAFETY: HEARTGARD has shown a wide margin of safety at the recommended dose level in dogs (See PRECAUTIONS for exceptions) 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 Chewables in a heartworm disease preventive program.

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 support the safety of HEARTGARD products in dogs, including Collies, when used as recommended.

HOW SUPPLIED: HEARTGARD Chewables are available in three dosage strengths (See DOSAGE section) for dogs of different weights. Each strength comes in convenient cartons of 6 chewables, packed 10 cartons per tray.

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Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096

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Heartgard® (ivermectin)

**Chewables
for Cats**

CHEWABLES FOR CATS

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

INDICATIONS: For use in cats to prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection, and for the removal and control of adult and immature hookworms (*Ancylostoma tubaeforme* and *A. braziliense*).

DOSAGE: HEARTGARD® for Cats should be administered orally at monthly intervals at the recommended minimum dose level of 24 mcg of ivermectin per kg (10.9 mcg/lb.) of body weight. The recommended dosage schedule for prevention of feline heartworm disease and control of hookworm is as follows:

Cat Weight lb	HEARTGARD for Cats Chewables per month	Ivermectin content
Up to 5 lb	1	55 mcg
5 to 15 lb	1	165 mcg

For cats over 15 lb., use the appropriate combination of chewables.

HEARTGARD for Cats is recommended for use in cats 6 weeks of age and older.

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. HEARTGARD for Cats can be offered to the cat by hand or may be added to a small amount of cat food. If manual dosing is required, the chewable should be broken into pieces for administration. Food should be routinely available during the day of treatment administration. If cats are fasted, or if the chewable is not broken into pieces for manual dosing, then reduced absorption may result. A relationship between reduced absorption and reduced efficacy has not been established.

Care should be taken to see that the cat consumes the complete dose. 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 with a new chewable is recommended. Fragments of chewables have occasionally been observed in the feces of some cats; efficacy of the product was not adversely affected.

HEARTGARD for Cats should be given at monthly intervals when mosquitoes potentially carrying infective heartworm larvae are active. The initial dose must be given within a month (30 days) after the cat's first exposure to mosquitoes. The final dose must be given within a month (30 days) after the cat's last exposure to mosquitoes. For optimal performance, HEARTGARD for Cats must be given once a month on or about the same date. If treatment is delayed, whether by a few days or many, immediate treatment with HEARTGARD for Cats and resumption of the recommended dosing regimen will minimize the opportunity for development of adult heartworm.

It is recommended that cats should be tested for existing heartworm infection prior to starting treatment with HEARTGARD for Cats. Cats already infected with adult heartworms can be given HEARTGARD for Cats monthly to prevent further infections.

Monthly treatment with HEARTGARD® (ivermectin) for Cats also provides effective removal and control of adult and immature hookworms (*A. tubaeforme* and *A. braziliense*).

SAFETY: In the clinical studies involving more than 3000 doses of HEARTGARD for Cats, observations reported within 24 hours of treatment included vomiting in ≤ 0.3% and diarrhea in ≤ 0.2% of the doses administered. There were no statistical differences between HEARTGARD for Cats and the product vehicle (control) for these observations.

A wide margin of safety was demonstrated in clinical trials at the recommended dose level in cats and kittens 6 weeks of age and older and in laboratory studies in cats with circulating microfilariae of *D. immitis*. A wide margin of safety has also been demonstrated at 3 times the recommended dose in pregnant or breeding queens and breeding toms. No adverse effects were observed in either male or female cats or their offspring in breeding studies. A 30-fold safety margin over the minimum recommended dosage was established in a single dose tolerance study. In growing kittens dosed monthly for 8 consecutive doses, one cat given 5 times the market dose vomited and a second cat in this group experienced diarrhea within 24 hours of the initial treatment. In clinical trials, many commonly used flea control products, anthelmintics, vaccines, antibiotics and steroid preparations were administered with HEARTGARD for Cats without incident.

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>.

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.

STABILITY: Store at controlled room temperature of 68°F - 77°F (20°C - 25°C). Excursions between 59°F - 86°F (15°C - 30°C) are permitted.

HOW SUPPLIED: HEARTGARD for Cats is available in two dosage strengths (see DOSAGE section) for cats of different weights. Each strength comes in a convenient carton of 6 chewables, packed 10 cartons per tray.

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