

HEARTGARD® TABLETS

Rx

Merial

Parasiticide-Oral

(ivermectin)

NADA No.: 138-412

Active Ingredient(s): Each tablet contains either:

Ivermectin	68 mcg, 136 mcg or 272 mcg
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Indications: For use in dogs to prevent canine heartworm disease. HEARTGARD® (ivermectin) prevents heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection.

Dosage and Administration: Dosage: HEARTGARD® 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) of body weight (See Administration). The recommended dosage schedule for prevention of canine heartworm disease is as follows:

Dog Weight	Tablets Per Month	Ivermectin Per Tablet	Color on 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 lb the appropriate combination of tablets.

HEARTGARD® is recommended for use in dogs 6 weeks of age or older.

Administration: The HEARTGARD® tablet should be given so that dogs swallow the whole tablet. (The tablet may be wrapped in food to encourage consumption.) 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® 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 in a heartworm disease prevention 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 optimum 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 HEARTGARD® and resumption of the recommended dosing regimen minimizes the opportunity for the development of adult heartworms.

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

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

All dogs should be tested for existing heartworm infection before starting treatment with HEARTGARD® (ivermectin) Tablets 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 the treatment of some dogs that have circulating microfilariae.

Warning(s): Keep this and all drugs out of the reach of children. In case of ingestion by human, clients should be advised to contact a physician immediately. Physicians may contact a Poison Control Center for advice concerning cases of ingestion by humans.

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.

Trial Data: Safety: HEARTGARD® has shown a wide margin of safety at the recommended dose level in dogs (See Cautions 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® 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.

Presentation: HEARTGARD® is available in three dosage strengths (see Dosage section) for dogs of different weights. Each strength comes in a convenient carton of 6 or 9 tablets, packed 10 cartons per tray.

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Disclaimer: Every effort has been made to ensure the accuracy of the information published. However, it remains the responsibility of the readers to familiarize themselves with the product information contained on the product label or package insert. Compendium Code No.: 08491028