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HEARTGARD[®] TABLETS FOR DOGS



Merial

(ivermectin)

NADA 138-412, Approved by the FDA

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. HEARTGARD[®] prevents heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection.

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 and 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 first exposure to mosquitoes. The final dose must be given within a month (30 days) after the 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 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 a month (30 days) after infection and, as a result, prevent the development of the adult stage.

PRECAUTIONS: 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.

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.

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.

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 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 is available in three dosage strengths (See DOSAGE section) for dogs of different weights. Each strength comes in a convenient carton of 6 tablets, packed 10 cartons per tray.

Store at controlled room temperature 68° - 77°F (20° - 25°C).

For customer assistance, please contact Merial at 1-888-637-4251.

Marketed by Merial Limited, Duluth, GA 30096-4640

Made in U.S.A.

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