

Label

Use/Dose

MERCK ANIMAL HEALTH Intervet Inc.

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Tri-Heart® Plus



Intervet/Merck Animal Health

(ivermectin/pyrantel)

Chewable Tablets

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: Tri-Heart® Plus 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	Chewable Tablets per Month	Ivermectin Content	Pyrantel Content	Color Coding on Blister Card and Carton
Up to 25 lbs	1	68 mcg	57 mg	Blue
26 to 50 lbs	1	136 mcg	114 mg	Green
51 to 100 lbs	1	272 mcg	227 mg	Brown

Tri-Heart® Plus is recommended for dogs 6 weeks of age and older. For dogs over 100 lbs, use the appropriate combination of these tablets.

ADMINISTRATION: Remove only one chewable tablet at a time from the blister card. Because most dogs find Tri-Heart® Plus palatable, the product can be offered to the dog by hand. Alternatively, it may be added intact to a small amount of dry 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.

Tri-Heart® 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 Tri-Heart® 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 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 Tri-Heart® Plus and resumption of the recommended dosing regimen minimizes the opportunity for the development of adult heartworms.

Monthly treatment with Tri-Heart® 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: Tri-Heart® Plus (ivermectin/pyrantel) 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. Tri-Heart® Plus chewable tablets are also effective against canine ascarids (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*).

ACCEPTABILITY: In acceptability trials, Tri-Heart® Plus is shown to be a palatable 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 Tri-Heart® 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 Tri-Heart® Plus.

While some microfilariae may be killed by the ivermectin in Tri-Heart® Plus at the recommended dose level, Tri-Heart® 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 at controlled room temperature of 59-86° F (15-30° C). Protect product from light.

ADVERSE REACTIONS: In clinical field 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 at the recommended dose: 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, contact Merck Animal Health at 1-800-224-5318 or www.TriHeartPlus.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

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, anthelmintics, 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: Tri-Heart® Plus is available in three dosage strengths (See DOSAGE section) for dogs of different weights. Each strength comes in convenient packs of 6 chewable tablets.

Manufactured for: Intervet Inc. a subsidiary of Merck & Co. Inc., Madison, NJ 07940

Manufactured by: Diamond Animal Health, Inc., a wholly owned subsidiary of Heska Corporation, Des Moines, IA 50327

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