

# IVERHART MAX<sup>®</sup>

(ivermectin/pyrantel pamoate/praziquantel)

## Soft Chew

For oral use in dogs only.

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

**Description:** IVERHART MAX<sup>®</sup> Soft Chew is a combination of three anthelmintics (ivermectin/pyrantel pamoate/praziquantel). The soft chews are available in four sizes in color-coded packages for oral administration to dogs according to their weight (see **Dosage and Administration**).

**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 roundworms (*Toxocara canis*, *Toxascaris leonina*), hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*), and tapeworms (*Dipylidium caninum*, *Taenia pisiformis*).

**Dosage and Administration:** IVERHART MAX Soft Chew should be administered orally at monthly intervals and the recommended minimum dose level of 6 mcg of ivermectin per kilogram (2.72 mcg/lb), 5 mg of pyrantel (as pamoate salt) per kg (2.27 mg/lb), and 5 mg of praziquantel per kg (2.27 mg/lb) of body weight, as follows:

Dog Weight Pounds	Soft Chew per Month	Soft Chew Size	Ivermectin Content	Pyrantel Pamoate Content	Praziquantel Content
6.0 to 12	1	Toy	34 mcg	28.5 mg	28.5 mg
12.1 to 25	1	Small	68 mcg	57 mg	57 mg
25.1 to 50	1	Medium	136 mcg	114 mg	114 mg
50.1 to 100	1	Large	272 mcg	228 mg	228 mg

IVERHART MAX Soft Chew is recommended for dogs 8 weeks of age or older. For dogs over 100 lbs, use the appropriate combination of these soft chews.

Remove only one dose at a time from the packaging. Return the remaining soft chew(s) to their box to protect from light. The soft chew can be offered to the dog by hand or added, intact, to a small amount of dog food. Care should be taken to ensure that the dog consumes the complete dose. The treated dog should be observed for a few minutes after administration to confirm that none of the dose has been lost or rejected. If it is suspected that any of the dose has been lost, redosing is recommended.

IVERHART MAX Soft Chew 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 preventative product in a heartworm disease prevention program, the first dose of IVERHART MAX Soft Chew must be given within a month (30 days) of the last dose of the former medication. A heartworm test should be performed prior to switching heartworm preventative products.

If the interval between doses exceeds a month (30 days), the effectiveness of ivermectin can be reduced. Therefore, for optimal performance, the soft chew 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 IVERHART MAX Soft Chew and the recommended dosing regimen will minimize the opportunity for the development of adult heartworms.

### Warnings:

**For use in dogs only. Keep this and all drugs out of reach of children and pets. In safety studies with ivermectin/pyrantel pamoate/praziquantel tablets, testicular hypoplasia was observed in some dogs receiving 3 and 5 times the maximum recommended dose monthly for 6 months (see **Animal Safety**).**

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.

**Precautions:** Use with caution in sick, debilitated, or underweight animals and dogs weighing less than 10 lbs (see **Animal Safety**). The safe use of this drug has not been evaluated in pregnant or lactating bitches.

All dogs should be tested for existing heartworm infection before starting treatment with IVERHART MAX Soft Chew, which is not effective against adult *Dirofilaria immitis*. Infected dogs should be treated to remove adult heartworms and microfilariae before initiating a heartworm prevention program.

While some microfilariae may be killed by the ivermectin in IVERHART MAX Soft Chew at the recommended dose level, IVERHART MAX Soft Chew 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.

**Adverse Reactions:** In a field study with IVERHART MAX Soft Chew, self-limiting adverse reactions, including vomiting, diarrhea, lethargy, difficulty swallowing, excessive salivation, increased water consumption, and coughing were reported. Self-limiting adverse reactions, including lethargy, limpness, salivation, shaking, diarrhea, decreased appetite, licking lips, and belching were reported between 20 minutes and 72 hours following treatment in a field study with ivermectin/pyrantel pamoate/praziquantel tablets.

In field studies with ivermectin/pyrantel pamoate tablets, vomiting or diarrhea within 24 hours of dosing was rarely observed (1.1% of administered doses). The following adverse reactions have been reported in dogs following the use of ivermectin products: depression/lethargy, vomiting, anorexia, diarrhea, mydriasis, ataxia, staggering, convulsions, and hypersalivation.

To report suspected adverse events, for technical assistance, or to obtain a copy of the Safety Data Sheet (SDS), contact Virbac AH, Inc. at 1-800-338-3659 or us.virbac.com. For additional information about adverse drug experience reporting for animal drugs, contact the FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

**Effectiveness:** Prevention of the tissue larval stage of heartworm (*Dirofilaria immitis*) and the elimination of the adult stage of hookworm (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*), roundworm (*Toxocara canis*, *Toxascaris leonina*), and tapeworm (*Dipylidium caninum*, *Taenia pisiformis*) infections in dogs was demonstrated in well-controlled laboratory studies.

**Palatability:** In a field study of 132 dogs, IVERHART MAX Soft Chew was offered once monthly for 3 months. The dogs voluntarily consumed 86.3% of the doses from the owner's hand or from a bowl within 5 minutes, 13.0% accepted the dose when it was offered in food or administered by placing onto the back of the dog's tongue (pilling), and 0.7% of the doses were unable to be administered.

**Animal 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 dose level of 6 mcg/kg) than dogs of other breeds. At elevated doses, sensitive dogs showed more adverse reactions, which included mydriasis, depression, ataxia, tremors, drooling, paresis, recumbency, excitability, stupor, coma, and death. No signs of toxicity were seen at 10 times the recommended dose (27.2 mcg/lb) in sensitive Collies. Data from these studies support the safety of ivermectin products in dogs, including Collies, when used at the label recommended dose.

Because ivermectin and praziquantel are approximately 30% more bioavailable in the IVERHART MAX Soft Chew than in the ivermectin/pyrantel pamoate/praziquantel tablets used in the following target animal safety studies, the margin of safety is narrower than reported in these studies. The potential for adverse reactions may be greater in individual dogs administered IVERHART MAX Soft Chew than ivermectin/pyrantel pamoate/praziquantel tablets.

In a target animal safety study using ivermectin/pyrantel pamoate/praziquantel tablets, doses were administered to 8-week-old Beagle puppies at one, three, and five times the maximum recommended dose of 12.5 mcg/kg ivermectin, 10.47 mg/kg pyrantel, and 10.47 mg/kg praziquantel. The dogs were treated every 30 days for 6 months. Vomiting within 6 hours of dosing and soft or watery feces within 24 hours of dosing were observed. Other observations during the study were: ano-genital swelling, lethargy, head movements, shallow, audible or difficult breathing, and salivation. One dog in the 5X group had tremors and decreased activity. All of these signs were transient. No treatment was required. Histopathology showed testicular hypoplasia in the 3X and 5X groups (see **Warnings**).

In a laboratory safety study using ivermectin/pyrantel pamoate/praziquantel tablets, 12-week-old Beagle puppies receiving 3 and 5 times the recommended dose once weekly for 13 weeks demonstrated a dose-related decrease in testicular maturation compared to controls. In this study, all treated puppies had significantly higher cholesterol levels compared to untreated controls.

In a reproductive safety study, adult males were treated at 37.5 mcg/kg ivermectin, 31.4 mg/kg pyrantel, and 31.4 mg/kg praziquantel every 14 days during two full spermatogenic cycles (112 days). The quality of semen and reproductive health were not affected by treatment. Treatment-related vomiting and soft feces were reported during this study.

In a study of the effectiveness of ivermectin/pyrantel pamoate/praziquantel tablets for the treatment of *Toxocara canis*, one 8.1 lb, 72-day-old puppy died 6 days after administration of the label dose. This puppy and many other puppies in the study had high worm burdens and were reported to have diarrhea, sometimes bloody, frequently before and after treatment. Dehydration and signs of anemia (pale mucous membranes) were the only abnormal gross necropsy finding observed. No definitive cause was determined. In a 90-day field study using ivermectin/pyrantel pamoate/praziquantel tablets, the most serious adverse reactions (lethargy, limpness, and salivation) were seen in dogs weighing less than 10 lbs (see **Precautions**).

**Storage Information:** Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (59°F to 86°F).

**How Supplied:** IVERHART MAX Soft Chew is available in four dosage strengths (see **Dosage and Administration**) for dogs of different weights. Each strength comes in a package of 6 soft chews.

NADA 141-441, Approved by FDA.

Manufactured by:

Virbac AH, Inc.  
Fort Worth, TX 76137 USA  
Phone: 1-800-338-3659

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