IVERHART MAX® Chew
(ivermectin/pyrantel pamoate/praziquantel)

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® Chew is a combination of three anthelmintics (ivermectin/pyrantel pamoate/praziquantel). The 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, Toxacarasis leonina), hookworms (Ancylostoma caninum, Uncinaria stenocephala, Ancylostoma braziliense), and tapeworms (Dipylidium caninum, Taenia pisiformis).

Dosage and Administration: IVERHART MAX 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:

<table>
<thead>
<tr>
<th>Dog Weight Pounds</th>
<th>Chew per Month</th>
<th>Chew Size</th>
<th>Ivermectin Content</th>
<th>Pyrantel Pamoate Content</th>
<th>Praziquantel Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0 to 12</td>
<td>1</td>
<td>Toy</td>
<td>34 mcg</td>
<td>28.5 mg</td>
<td>28.5 mg</td>
</tr>
<tr>
<td>12.1 to 25</td>
<td>1</td>
<td>Small</td>
<td>68 mcg</td>
<td>57 mg</td>
<td>57 mg</td>
</tr>
<tr>
<td>25.1 to 50</td>
<td>1</td>
<td>Medium</td>
<td>136 mcg</td>
<td>114 mg</td>
<td>114 mg</td>
</tr>
<tr>
<td>50.1 to 100</td>
<td>1</td>
<td>Large</td>
<td>272 mcg</td>
<td>228 mg</td>
<td>228 mg</td>
</tr>
</tbody>
</table>

IVERHART MAX 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 chew(s) to their box to protect from light. The 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 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 Chew must be given within a month (30 days) after the last dose of the former medication. A heartworm test should be performed prior to and 6 months after switching heartworm preventative products.

If the interval between doses exceeds a month (30 days), the effectiveness of ivermectin may be reduced. Therefore, for optimal performance, the 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 Chew and resumption of 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.

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, 3.1 mg/kg pyrantel and 3.1 mg/kg praziquantel every 14 days during two full spermatogenetic 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 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 (lactary, limpness, and salivation) were seen in dogs weighing less than 10 lbs (see Precautions).

Adverse Reactions: In a field study with IVERHART MAX Chew, self-limiting adverse reactions, including vomiting, diarrhea, lethargy, difficulty swallowing, excessive salivation, decreased 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/praziquantel 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.

Adverse Reactions: Lethargy, tremors, tremors, decreased activity, and increased body temperature were observed in some dogs receiving 3 and 5 times the maximum recommended dose monthly.

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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). Protect product from light.

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

Approved by FDA under NADA # 141-441

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