ProHeart® 6 (moxidectin)

**SAFETY**

**Zoetis**

**ProHeart 6** is indicated for the treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections in dogs six months of age and older. It is not recommended for use in heartworm positive dogs (see WARNINGS). ProHeart 6 is indicated for use in dogs six months of age and older for the prevention of heartworm disease caused by *D. immitis* and *A. caninum* for six months. It should be administered within one month of the dog’s first exposure to mosquitoes. Prior to administration of ProHeart 6, dogs should be tested for existing heartworm infections. Infected dogs should be treated with the appropriate therapy and ProHeart 6 should be administered six months later. The safety and effectiveness of ProHeart 6 has not been evaluated in dogs less than 6 months of age.

**CONSTITUTION PROCEDURES**

1.  Shake the microsphere vial to break up any aggregates prior to constitution. The recommended dose rate of 0.17 mg moxidectin/kg body weight is the tissue larval stage. The larval and adult stages of the canine hookworms, *Ancylostoma caninum* and *Uncinaria stenocephala*, are susceptible. Moxidectin has activity resulting in paralysis and death of affected parasites. The stage of the canine heartworm affected at treatment is delayed, gently roll the dosing syringe prior to injection to maintain a uniform suspension and accurate dosing.

2.  Insert the enclosed 25G vent needle into the microsphere vial.

3.  Withdraw 0.05 mL of suspension/kg body weight into an appropriately sized syringe fitted with an 18G or 20G hypodermic needle. Dose: The recommended subcutaneous dose is 0.05 mL of the constituted suspension/kg body weight (0.0227 mL/kg). This amount of suspension will provide 0.17 mg moxidectin/kg body weight (0.0773 mg/kg). To ensure accurate dosing, calculate each dose based on the dog’s weight at the time of treatment. Do not overdose puppies in anticipation of their expected adult weight. The following dosage chart may be used as a guide.

<table>
<thead>
<tr>
<th>Dog Wt</th>
<th>kg</th>
<th>Dose Volume</th>
<th>mL/Dog</th>
<th>Dog Wt</th>
<th>kg</th>
<th>Dose Volume</th>
<th>mL/Dog</th>
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<tbody>
<tr>
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<td>66</td>
<td>30</td>
<td>1.50</td>
<td>3.00</td>
</tr>
</tbody>
</table>

*Injection Technique: The two-part sustained release product must be mixed at least 30 minutes prior to the intended time of use (see CONSTITUTION PROCEDURES for initial mixing instructions). Once constituted, swirl the bottle gently before every use to uniformly re-suspend the microspheres. Withdraw 0.05 mL of suspended/kg body weight into a properly sized syringe fitted with an 18G or 20G hypodermic needle. Dose: The recommended subcutaneous dose is 0.05 mL of the constituted suspension/kg body weight (0.0227 mL/kg). This amount of suspension will provide 0.17 mg moxidectin/kg body weight (0.0773 mg/kg). To ensure accurate dosing, calculate each dose based on the dog’s weight at the time of treatment. Do not overdose puppies in anticipation of their expected adult weight. The following dosage chart may be used as a guide."

**ADVERSE REACTIONS**

Injection site observations were recorded during effectiveness and safety studies. In clinical studies, ProHeart 6 was administered at six-month intervals to client-owned dogs under field conditions. There were no reports of injection site reactions in these field studies. In short-term evaluations of the injection sites revealed no abnormalities. ProHeart 6 was administered at six-month intervals to client-owned dogs under field conditions. There were no reports of injection site reactions in these field studies. In short-term evaluations of the injection sites revealed no abnormalities. In well controlled clinical field studies, ProHeart 6 was used in conjunction with a variety of veterinary products including anthelmintics, antibiotics, and vaccines. Adverse reactions were noted in some dogs from all treated groups. These injection site reactions appeared as quickly as 8 hours post injection and lasted up to 2 weeks. Some dogs treated with ProHeart 6 in laboratory effectiveness studies developed transient, localized inflammatory injection site reactions. These injection site reactions were visible for up to 3 weeks after injection. Histologically, well-defined granulomas were observed in some dogs at approximately 5 months after injection.

**STORAGE INFORMATION**

Store the constituted product at or below 25°C (77°F). Do not expose to light for extended periods after reconstitution. After reconstitution, the product is stable for 4 weeks stored under refrigeration at 2°C to 8°C (36°F to 46°F).

**HOW SUPPLIED**

ProHeart 6 is available in the following three package sizes.

1. **1-Pack**
   - 20 mL vial product:
     - 10 mg/mg microsphere microspheres
   - 598 mg/vial
   - 1 - Sterile vehicle - 17 mL vial
   - 598 mg/vial

2. **2-Pack**
   - 20 mL vial product:
     - 10 mg/mg microsphere microspheres
   - 598 mg/vial
   - 1 - Sterile vehicle - 17 mL vial
   - 598 mg/vial

3. **10-Pack**
   - 20 mL vial product:
     - 10 mg/mg microsphere microspheres
   - 598 mg/vial
   - 1 - Sterile vehicle - 17 mL vial
   - 598 mg/vial

For a copy of the Material Safety Data Sheet (MSDS) or to report a suspected adverse reaction, call Zoetis Inc. at 1-888-963-8471.

**Revised July 2014**