**ProHeart® 6 (moxidectin)**

For Extended-Release Injectable Suspension for Dogs

**CAUTION**

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

ProHeart 6 (moxidectin) for extended-release injectable suspension consists of two separate vials: One vial contains 10% moxidectin sterile microspheres and the second vial contains a specifically formulated sterile vehicle for constitution with the microspheres. The sterile vehicle is a 0.5% sodium chloride solution that contains water, 0.01% butylated hydroxytoluene, 0.02% propylparaben, and 0.17% methylparaben. Each ml of constituted drug product contains 3.4 mg moxidectin, 3.1% glycerin triisostearate, 2.4% hydroxypropyl methylcellulose, 0.04% sodium chloride, 0.17% methylparaben, propylparaben, and 0.001% butylated hydroxytoluene. Hydrochloric acid is used to adjust pH. The constituted product may appear as a hazy to milky suspension.

**INDICATIONS**

ProHeart 6 is indicated for use in dogs six months of age and older for the prevention of heartworm disease caused by *Dirofilaria immitis* for 6 months.

ProHeart 6 is indicated for the treatment of existing larval and adult hookworm (*Ankylostoma caninum* and *Uncinaria stenocephala*) infections.

**DOSE AND ADMINISTRATION**

Always provide Client Information Sheet and review with owners before administering ProHeart 6. The owner should be advised to observe their dog for adverse drug events including those described on the sheet.

**TREATMENT DOSES**

The recommended dose for adult dogs weighing >20 kg is 1.5 mL (0.075 mg/kg body weight) with 10% moxidectin in 0.5% sodium chloride vehicle supplied. Dosage adjustment is not required for bodyweight variations of ±15%.

**FREQUENCY OF TREATMENT**

To prevent heartworm infections, give 1 dose every 6 months. A single dose can be administered up to 5 times the recommended dose in 7-8 month old puppies did not cause any systemic adverse effects. In some cases, death has been reported as an outcome of the adverse events listed above.

**CONTRAINDICATIONS**

ProHeart 6 is contraindicated in animals previously found to be hypersensitive to this drug or ProHeart 12.

**HUMAN WARNINGS**

Not for human use. Keep this and all drugs out of the reach of children.

May be slightly irritating to the eyes. May cause slight irritation to the upper respiratory tract if inhaled. May be harmful if swallowed. If contact with the eyes occurs, rinse thoroughly with water for 15 minutes and seek medical attention immediately. Accidental swallowing may result in an allergic reaction in a human or a cat immediately. The Safety Data Sheet (SDS) contains more detailed occupational safety information.

**WARNINGS**

Anaphylactic and anaphylactoid reactions may occur in some dogs following administration of ProHeart 6 alone or with vaccines. In some cases, these reactions have resulted in death following administration of moxidectin microspheres (see POST-APPROVAL EXPERIENCE). Anaphylactic and anaphylactoid reactions should be treated immediately with the same measures used to treat hypersensitivity reactions to vaccines and other injectable products. Always provide Client Information Sheet and review with owners before administering ProHeart 6. The owner should be advised to observe their dog for adverse drug events including those described on the sheet.

Do not administer ProHeart 6 to dogs who are sick, debilitated, underweight or who have a history of weight loss.

**PRECAUTIONS**

Prior to administration of ProHeart 6, the health of the patient should be assessed by a thorough medical history, physical examination and diagnostic tests as deemed necessary by the veterinarian.

Caution should be used when administering ProHeart 6 to dogs with pre-existing allergic disease, including food allergy, atopy, and flea allergy dermatitis. (see WARNINGS).

Care should be taken to avoid administering ProHeart 6 concurrently with vaccinations. Adverse reactions, including anaphylaxis, have been reported following the concomitant use of moxidectin microspheres and vaccines (see WARNINGS and POST-APPROVAL EXPERIENCE).

ProHeart 6 should not be used more frequently than every 6 months.

The effectiveness of ProHeart 6 has not been evaluated in dogs less than 6 months of age.

Prior to administration of ProHeart 6, dogs should be tested for existing heartworm infections. Infected dogs should be treated with an adulticide to reduce adult heartworms. ProHeart 6 is not effective against adult 24-48 hours after the start of treatment. Dosage adjustment is not required for bodyweight variations of ±15%.

**ADVERSE REACTIONS**

In a laboratory safety study, ProHeart 6 was administered at 1, 3 and 5 times the recommended dose to 7-8 month old puppies that had previously received ivermectin. Problems experienced lethargy following the initial injection of ProHeart 6. The dog never recovered and died 3 months later (see WARNINGS).

In healthy dogs, ProHeart 6 administered up to 5 times the recommended dose in dogs did not cause any systemic adverse reactions. In some cases, death has been reported as an outcome of the adverse events listed above.

**STORAGE INFORMATION**

Store the unconstituted product at or below 25°C (77°F). Do not expose to light for extended periods of time. After reconstitution, store at or below 25°C (77°F). Allow suspension to stand for at least 30 minutes to allow large air bubbles to dissipate. Before every use, gently swirl the mixture to achieve uniform suspension. Do not refrigerate and do not freeze.

**CONSTITUTION PROCEDURES**

The two-part ProHeart 6 product must be used 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 use. Every use for a 1 mL syringe will require 1.0 mL of sterile vehicle from the vial.

**DOSAGE CHART**

<table>
<thead>
<tr>
<th>Dog Wt (kg)</th>
<th>Dose Volume (mL/Dog)</th>
<th>Dose Volume (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11-15</td>
<td>0.25</td>
<td>0.02</td>
</tr>
<tr>
<td>16-20</td>
<td>0.50</td>
<td>0.04</td>
</tr>
<tr>
<td>21-25</td>
<td>1.00</td>
<td>0.05</td>
</tr>
<tr>
<td>26-30</td>
<td>1.25</td>
<td>0.06</td>
</tr>
<tr>
<td>31-40</td>
<td>1.50</td>
<td>0.07</td>
</tr>
<tr>
<td>41-50</td>
<td>2.00</td>
<td>0.08</td>
</tr>
<tr>
<td>51-60</td>
<td>3.00</td>
<td>0.10</td>
</tr>
</tbody>
</table>

**Dosage Volume** is a volume of the unique sterile vehicle (0.5% sodium chloride) required to reconstitute the microspheres in each vial.

**ADVERSE REACTIONS**

Immune: anaphylaxis and/or anaphylactoid reactions, urticaria, head/face edema, pruritus, pale mucous membranes, collapse, cardiovascular shock, erythema, immune-mediated hemolytic anemia, immune-mediated thrombocytopenia (signs reflected in other system categories could be related to allergic reactions, i.e. gastrointestinal, dermatologic, and hematologic).

Gastrointestinal: vomiting (with or without blood), diarrhea with or without blood, hypersalivation

General: depression, lethargy, anorexia, fever, weight loss, weakness

Dermatological: injection site pruritus, swelling, erythema, pyotraumatic dermatitis

Hepatic: elevated liver enzymes, hyperproteinemia, hyperbilirubinemia, hepatopathy

Urinary: elevated BUN, elevated creatinine, hematuria, polydypsia, polyuria

Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm positive dogs.

In cases, death has been reported as an outcome of the adverse events listed above.