### FEATURES:

<table>
<thead>
<tr>
<th>Compliance</th>
<th>ProHeart® 12 (moxidectin) provides the highest level of compliance possible for any canine heartworm prevention product for a full year.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• No monthly doses for dog owners to remember. ProHeart 12 makes compliance easy – and there are no gaps in protection for a full year.</td>
</tr>
<tr>
<td></td>
<td>• ProHeart 12 provides dog owners with peace of mind and convenience, as once-yearly doses align with regular veterinary wellness visits.</td>
</tr>
<tr>
<td>Efficacy</td>
<td>In three well-controlled studies, ProHeart® 12 (moxidectin) demonstrated 100% efficacy against heartworm* disease. In a separate field study, ProHeart 12 was 100% effective even in areas where resistant isolates have been identified.</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>ProHeart® 12 (moxidectin) helps sustain the health of the veterinarian practice and pharmacy because it is administered exclusively at the veterinary clinic. This keeps revenue within the hospital pharmacy and insulates the clinic against purchases made at online pharmacies or big box stores.</td>
</tr>
</tbody>
</table>

### IMPORTANT SAFETY INFORMATION:

Use PROHEART 12 in dogs 12 months of age or older. Do not administer to dogs that are sick, debilitated, underweight, have a history of weight loss, or to those previously found to be hypersensitive to the drug. Hypersensitivity reactions may occur in some dogs when PROHEART 12 is administered alone or with vaccines. Anaphylactic and anaphylactoid reactions can result in death and should be treated immediately with the same measures used to treat hypersensitivity reactions to vaccines and other injectable products. The most common reported side effects in clinical trials were vomiting, lethargy, diarrhea, and anorexia. People should avoid inhalation, contact with eyes, or accidental self-injection. Certification is required before veterinarians and staff administer PROHEART 12.

See full Prescribing Information attached.
12 months. 1 dose. Multiple benefits with **ProHeart 12** (moxidectin).

**COMPLIANCE.**  
*ProHeart 12* provides veterinary-team controlled compliance and prevents missed monthly doses.

**EFFICACY.**  
*ProHeart 12* was tested in a field study in the Lower Mississippi River Valley* and was 100% effective.²

**PHARMACY PROTECTION.**  
*ProHeart 12* purchases remain within your pharmacy instead of being filled elsewhere.

*Where resistant strains of heartworm disease have been identified.


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**Sound Byte**

First, always ask if a Zoetis representative has visited the practice recently:  
*Doctor, have you recently been introduced to ProHeart® 12 (moxidectin), the only heartworm disease preventative that provides 12 months of protection in 1 injection?*  
If **YES**, confirm and discuss benefits.  
If **NO**, engage/detail the customer as the primary contact.

**CONFIDENCE**  
I believe ProHeart® 12 helps eliminate concerns about compliance for 12 full months, keeping dogs protected year-round against potentially fatal heartworm disease while also providing peace-of-mind to pet owners.

**INVITATION (neutral)**  
Let’s discuss new ProHeart® 12 from Zoetis…

**CUSTOMER’S DECISION**  
…so you can feel confident that your canine patients will be protected against heartworm disease for a full year while ensuring the health of your clinic pharmacy as well.
ProHeart® 12 (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.

DESCRIPTION
ProHeart 12 (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 injection with the microspheres. A clear or translucent appearance of the vehicle is normal. Each mL of constituted drug product contains 10 mg moxidectin, 9% glyceryl tristearate, 2.25% hydroxypropyl methylcellulose, 0.81% sodium chloride, 0.16% methylparaben, 0.02% propylparaben and 0.004% butylated hydroxyanisole. Hydrochloric acid is used to adjust pH. The constituted product may appear as a hazy to milky suspension.

INDICATIONS
ProHeart 12 is indicated for use in dogs 12 months of age and older for the prevention of heartworm disease caused by Dirofilaria immitis for 12 months.

ProHeart 12 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 12.

The owner should be advised to observe their dog for adverse drug events including those described on the sheet. The Client Information Sheet is attached to this package insert and available online at http://www.proheart12.com for reprinting to provide to the owner.

The recommended subcutaneous dose is 0.05 mL of the constituted suspension/kg body weight (0.023 mL/lb). This amount of suspension will provide 0.5 mg moxidectin/kg body weight (0.23 mg/lb). To ensure accurate dosing, calculate each dose based on the dog’s weight at the time of treatment. The following table provides a guide for weight specific dose volumes.

Table 1: Dosage Guide

<table>
<thead>
<tr>
<th>Dog Weight (Pounds)</th>
<th>Kilograms (kg)</th>
<th>Dose Volume* mL/Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 lb</td>
<td>5 kg</td>
<td>0.25</td>
</tr>
<tr>
<td>22 lb</td>
<td>10 kg</td>
<td>0.50</td>
</tr>
<tr>
<td>33 lb</td>
<td>15 kg</td>
<td>0.75</td>
</tr>
<tr>
<td>44 lb</td>
<td>20 kg</td>
<td>1.00</td>
</tr>
<tr>
<td>55 lb</td>
<td>25 kg</td>
<td>1.25</td>
</tr>
<tr>
<td>66 lb</td>
<td>30 kg</td>
<td>1.50</td>
</tr>
<tr>
<td>77 lb</td>
<td>35 kg</td>
<td>1.75</td>
</tr>
<tr>
<td>88 lb</td>
<td>40 kg</td>
<td>2.00</td>
</tr>
<tr>
<td>99 lb</td>
<td>45 kg</td>
<td>2.25</td>
</tr>
<tr>
<td>110 lb</td>
<td>50 kg</td>
<td>2.50</td>
</tr>
<tr>
<td>121 lb</td>
<td>55 kg</td>
<td>2.75</td>
</tr>
<tr>
<td>132 lb</td>
<td>60 kg</td>
<td>3.00</td>
</tr>
</tbody>
</table>

*All dogs should be dosed at 0.05 mL suspension/kg body weight (0.023 mL/lb).

Injection Technique:
ProHeart 12 must be prepared at least 30 minutes prior to the first use by adding the sterile vehicle to the microspheres. See CONSTITUTION PROCEDURES for initial mixing instructions.

Swirl the constituted product gently before every use to uniformly re-suspend the microspheres.
Withdraw 0.05 mL of suspension/kg body weight (0.023 mL/lb) into an appropriately sized syringe fitted with an 18G or 20G hypodermic needle. Dose promptly after drawing into dosing syringe. If administration is delayed, gently roll the dosing syringe prior to injection to maintain a uniform suspension and accurate dosing.

Using aseptic technique, inject the product subcutaneously in the left or right side of the neck cranial to the scapula. No more than 3 mL should be administered in a single site. The location(s) of the injection site that resolved spontaneously within 24 hours of administration.

If contact with your skin occurs, wash thoroughly with water. May be irritating to the eyes. If product accidentally gets into your eyes, flush eyes thoroughly with water. In case of accidental ingestion, if skin or eye irritation occurs, contact a Poison Control Center or physician for treatment advice and show the package insert to the physician.

Take care to avoid accidental self-injection. In case of accidental self-injection, seek medical advice and show the package insert or the label to the physician. 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 12 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 12.

The owner should be advised to observe their dog for adverse drug events including those described on the sheet.

Do not administer ProHeart 12 to dogs who are sick, debilitated, underweight or who have a history of weight loss.

PRECAUTIONS
Prior to administration of ProHeart 12, the health of the patient should be assessed by a thorough medical history, physical examination and diagnostic testing as indicated (see WARNINGS).

Caution should be used when administering ProHeart 12 in dogs with pre-existing allergic disease, including food allergy, atopy, and flea allergy dermatitis. (see WARNINGS).

Caution should be used when administering ProHeart 12 concurrently with vaccinations. Adverse reactions, including anaphylaxis, have been reported following the concomitant use of moxidectin microspheres and vaccinations (see WARNINGS and POST-APPROVAL EXPERIENCE).

ProHeart 12 should not be used more frequently than every 12 months.

The effectiveness of ProHeart 12 has not been evaluated in dogs less than 12 months of age.

Prior to administration of ProHeart 12, dogs should be tested for existing heartworm infections. Infected dogs should be treated with an adulticide to remove adult heartworms. ProHeart 12 is not effective against adult O. immitis.

Caution should be used when administering ProHeart 12 to heartworm positive dogs (see ADVERSE REACTIONS).

ADVERSE REACTIONS
A well-controlled field study was conducted, including a total of 593 dogs (297 received two doses of ProHeart 12, 12 months apart and 296 received a monthly oral heartworm preventive as active control) ranging in age from 1 to 14 years. Over the 605-day study period, all observations of potential adverse reactions were recorded.

Table 2: Number of Dogs* with Adverse Reactions Reported During the ProHeart 12 Field Study

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ProHeart® 12 n=297 (%)</th>
<th>Active Control n=296 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vomiting</td>
<td>75 (25.3)</td>
<td>78 (26.4)</td>
</tr>
<tr>
<td>Lethargy</td>
<td>46 (15.5)</td>
<td>34 (11.5)</td>
</tr>
<tr>
<td>Diarrhea (with and without blood)</td>
<td>43 (14.5)</td>
<td>46 (15.5)</td>
</tr>
<tr>
<td>Anorexia</td>
<td>41 (13.8)</td>
<td>31 (10.5)</td>
</tr>
<tr>
<td>Seizures</td>
<td>10 (3.4)</td>
<td>7 (2.4)</td>
</tr>
<tr>
<td>Hepatopathy</td>
<td>8 (2.7)</td>
<td>3 (1.0)</td>
</tr>
<tr>
<td>Hypersalivation</td>
<td>7 (2.4)</td>
<td>3 (1.0)</td>
</tr>
<tr>
<td>Anaphylactic/hypersensitivity Reactions</td>
<td>6 (2.0)</td>
<td>4 (1.4)</td>
</tr>
</tbody>
</table>

*Some dogs may have experienced more than one adverse reaction or more than one occurrence of the same adverse reaction during the study.

Two ProHeart 12 (moxidectin) - treated dogs experienced anaphylactic/hypersensitivity-related clinical signs within the first 24 hours following the initial treatment. Both dogs responded to symptomatic treatment. One dog experienced hives and facial swelling that resolved in 24 hours. The second dog experienced redness and swelling of the face and paws, followed by vomiting, polydipsia, and elevated heart rate and was treated symptomatically. Signs resolved within 4 days. One dog was pre-treated before the second injection of ProHeart 12, and neither dog had a reaction to the second dose 12 months later. One active control-treated dog experienced anaphylactic/hypersensitivity-related clinical signs within the first 24 hours. The dog was withdrawn from the study prior to the second monthly dose.

Mild injection site reactions occurred in six ProHeart 12-treated dogs and were observed from one to seven days post dosing and included warmth, swelling and pruritus. One of these cases included mild pruritus at the injection site that resolved spontaneously within 24 hours of administration.

In a laboratory effectiveness study, dogs with 4- and 6-month-old heartworm infections administered moxidectin microspheres at a dose of 0.17 mg/kg experienced vomiting, lethargy and bloody diarrhea. These signs were more severe in the dogs with 4-month-old heartworm infections, including one dog that was recumbent and required supportive care, than in the dogs with older (6-month-old) infections.

Post-Approval Experience (2018): The following adverse events are based on post-approval adverse drug reaction reports for ProHeart 6. ProHeart 12 and ProHeart 6 are the same formulation, but ProHeart 12 is three times the concentration of ProHeart 6. Not all adverse reactions are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data. The following adverse events are listed in decreasing order of frequency by body system.

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

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

If contact with your skin occurs, wash thoroughly with water. May be irritating to the eyes. If product accidentally gets into your eyes, flush eyes thoroughly with water. In case of accidental ingestion, if skin or eye irritation occurs, contact a Poison Control Center or physician for treatment advice and show the package insert to the physician.

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

If contact with your skin occurs, wash thoroughly with water. May be irritating to the eyes. If product accidentally gets into your eyes, flush eyes thoroughly with water. In case of accidental ingestion, if skin or eye irritation occurs, contact a Poison Control Center or physician for treatment advice and show the package insert to the physician.
Constitution of the 10 mL vial product.

1. Shake the microsphere vial to break up any aggregates prior to constitution.
2. Using an 18G or 20G needle and sterile syringe withdraw 8 mL of the unique sterile vehicle from the vial.
3. Insert the enclosed 25G needle into the microsphere vial.
4. Slowly transfer the 8 mL of sterile vehicle into the microsphere vial through the stopper using the transfer needle and syringe.
5. Once the sterile vehicle has been added, remove the vent and transfer needles from the microsphere vial.
6. Discard unused sterile vehicle and needles.
7. Shake the microsphere vial vigorously until a thoroughly mixed suspension is produced. The product may appear as a hazy to milky suspension.
8. Allow suspension to stand for at least 30 minutes to allow large air bubbles to dissipate.
9. Before every use, gently swirl the mixture to achieve uniform suspension. The product may appear as a hazy to milky suspension.
10. Use a 1 mL or 3 mL syringe and an 18G or 20G needle for dosing. Dose promptly after drawing into dosing syringe. If administration is delayed, gently roll the dosing syringe prior to injection to maintain a uniform suspension and accurate dosing.

Storage Information
Store the unconstituted product at or below 25°C (77°F). Do not expose to light for extended periods of time. After constitution, the product is stable for 8 weeks stored under refrigeration at 2° to 8°C (36° to 46°F).

How Supplied
ProHeart 12 10 mL vial product is available in the following package sizes.

<table>
<thead>
<tr>
<th>Package Size</th>
<th>1-Pack</th>
<th>5-Pack</th>
<th>10-Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 10% moxidectin sterile microspheres- 889 mg/vial</td>
<td>5 - 10% moxidectin sterile microspheres- 889 mg/vial</td>
<td>10 - 10% moxidectin sterile microspheres- 889 mg/vial</td>
<td></td>
</tr>
<tr>
<td>1 - Sterile vehicle - 8 mL/vial</td>
<td>5 - Sterile vehicle - 8 mL/vial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 - Sterile vehicle - 8 mL/vial</td>
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<td></td>
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</tbody>
</table>

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