



**IT
ONLY
TAKES
ONE**

ProHeart[®] 12
(moxidectin)

ProHeartDVM.com

FEATURES:

BENEFITS:

Compliance

ProHeart 12 provides 12 months of guaranteed heartworm disease prevention compliance in a single dose.

- ProHeart 12 provides dog owners with peace of mind and convenience, as once-yearly doses align with regular veterinary wellness visits.

Efficacy

In three well-controlled studies, ProHeart 12 demonstrated 100% efficacy against heartworm disease.¹ In a separate field study, ProHeart 12 was 100% effective even in areas where resistant isolates have been identified.²

Pharmacy

ProHeart 12 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 helps insulate the clinic against purchases made at online pharmacies or big box stores.

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 page **XX** for prescribing information.

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12 months. 1 dose. Multiple benefits with **ProHeart 12.**



COMPLIANCE.

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



EFFICACY.

ProHeart 12 was tested in a field study including several sites in the Lower Mississippi River Valley* and was 100% effective²



PHARMACY PROTECTION.

ProHeart 12 purchases remain within your pharmacy instead of being filled elsewhere

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*Where resistant strains of heartworm disease have been identified.

¹ProHeart® 12 [package insert]. Kalamazoo, MI: Zoetis Inc. 2020.

²Study A161C-US-13-330. Data on file. Zoetis Inc.

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CHECK-OFF &
ECHO NOTES

First, always ask if a Zoetis representative has been in contact recently:

Doctor, have you been introduced to ProHeart 12, 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

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.

Neutral invitation

Let's discuss ProHeart 12 from Zoetis...

It's the 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.

Brief Summary of Prescribing Information.

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.

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 (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

RISK MINIMIZATION ACTION PLAN
The ProHeart 12 and ProHeart 6 Risk Minimization Action Plan (RiskMAP) provides educational materials to the veterinarian, veterinary staff, and the dog owner explaining the risks and proper use of ProHeart 12 and ProHeart 6. ProHeart 12 and ProHeart 6 are the same formulation, but ProHeart 12 is three times the concentration of ProHeart 6. ProHeart 12 and ProHeart 6 are for use in dogs only and are available through a restricted distribution program to veterinarians that have completed the RiskMAP training and certification module.

The ProHeart 12 and ProHeart 6 web-based training and certification module is available at <http://www.proheart12.com>. This website has important information on the safe and effective use of ProHeart 12 and ProHeart 6 for veterinarians.

Only veterinarians and veterinary technicians/assistants that have completed the training and are certified can administer ProHeart 12 and ProHeart 6. Veterinarians are expected to report all adverse events that occur in animals or humans to the manufacturer. Important safety information is included below:

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, or 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 *D. 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

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

*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 anaphylactoid/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 anaphylactoid/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 experience reporting 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.

Immune: anaphylaxis and/or anaphylactoid reactions, urticaria, head/facial 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 multiforme

Neurological: seizures, ataxia, trembling, hind limb paresis

Hematological: leukocytosis, anemia, thrombocytopenia

Respiratory: dyspnea, tachypnea, coughing

Hepatic: elevated liver enzymes, hypoproteinemia, hyperbilirubinemia, hepatopathy

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

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

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

Foreign market experience with ProHeart 12 includes similar voluntarily reported adverse events, including death, following administration of ProHeart 12.

For a copy of the Safety Data Sheet (SDS) or to report suspected adverse reactions, contact Zoetis at 1-888-963-8471. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

INFORMATION FOR DOG OWNERS
Always provide Client Information Sheet and review with owners before administering ProHeart 12. Owners should be advised of the potential for adverse reactions, including anaphylaxis, and be informed of the clinical signs associated with drug toxicity (see **WARNINGS**, **ADVERSE REACTIONS** and **POST-APPROVAL EXPERIENCE** sections.)

Owners should be advised to contact their veterinarian immediately if signs of toxicity are observed. The vast majority of patients with drug related adverse reactions have recovered when the signs are recognized and veterinary care, if appropriate, is initiated.

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.

1-Pack	5-Pack	10-Pack
1 - 10% moxidectin sterile microspheres- 889 mg/vial 1 - Sterile vehicle - 8 mL/vial	5 - 10% moxidectin sterile microspheres- 889 mg/vial 5 - Sterile vehicle - 8 mL/vial	10 - 10% moxidectin sterile microspheres- 889 mg/vial 10 - Sterile vehicle - 8 mL/vial

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