



# LAUNCH KIT

**YOUR SOURCE FOR SUCCESSFUL IMPLEMENTATION**

## **YOU’VE MADE THE SMART CHOICE TO USE PROHEART® 6 (MOXIDECTIN) IN YOUR CLINIC. NOW WHAT?**

Let this be your guide on how to successfully implement ProHeart 6. From getting your team on board to real-world advice from other clinics that offer ProHeart 6, you can choose the tips and tools that work best for your clinic. Now let’s get started!

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## A TEAM EFFORT

First things first: You need to ensure that all veterinarians, technicians and your entire healthcare team agree that ProHeart 6 is your clinic's choice for continuous heartworm disease prevention. Here are some suggestions for getting the entire team excited about ProHeart 6 being a part of your practice.

1. Hold a kickoff meeting to explain why offering ProHeart 6 is valuable to your clinic, and discuss the implementation process.
2. Right from the beginning, be sure to ask if anyone has questions or concerns about implementing ProHeart 6.
3. Identify a champion at the practice who will lead the ProHeart 6 implementation.
4. Develop a long-term program on how the team will implement ProHeart 6 with checkpoints along the way to ensure success.
5. Set up short, weekly update meetings to discuss how ProHeart 6 implementation is progressing, and address any concerns or questions.
6. All team members should become ProHeart 6 certified by going to [proheart6training.com](http://proheart6training.com).
7. Invite a Zoetis ELITE speaker to your clinic to discuss with your team how he/she successfully implemented ProHeart 6.
8. Encourage team members to use ProHeart 6 for their own dogs. Zoetis will provide free samples for use on team members' dogs.

**IMPORTANT SAFETY INFORMATION:** PROHEART 6 should be used in healthy dogs. Do not administer to sick, debilitated, underweight dogs or dogs that have a history of weight loss. Prior to administration, PROHEART 6 certified veterinarians should continue to assess patient health through a medical history, physical examination and if deemed appropriate, diagnostic testing. Continue to use caution when administering PROHEART 6 concurrently with vaccinations. Adverse events, including anaphylaxis, have been reported following the concomitant use of PROHEART 6 and vaccines. In some cases, anaphylactic reactions have resulted in death. Use with caution in dogs with pre-existing or uncontrolled allergic disease (food allergy, atopy or flea allergy dermatitis). Dogs receiving PROHEART 6 should be tested for existing heartworms as per the product label. In people, avoid PROHEART 6 contact with eyes. If contact with the eyes occurs, rinse thoroughly with water for 15 minutes and seek medical attention immediately. PROHEART 6 is available only to veterinarians through a restricted distribution program. Only certified veterinarians and staff can administer it. See [full Prescribing Information](#).

## HAVE FUN WITH IT

Get your team involved and excited. Help them own the process and create success.

1. Host a “ProHeart 6 Day” on a Saturday or another convenient day to promote heartworm disease awareness and encourage clients to protect their dogs with ProHeart 6.
2. Use promotional materials provided by Zoetis. Ask your Zoetis representative.
3. Raise awareness with American Heartworm Society materials from [heartwormsociety.org](http://heartwormsociety.org).
4. Set short-term (weekly) and long-term (monthly or quarterly) goals, and schedule frequent progress review meetings with your team. Your Zoetis representative can help.
5. Identify 100 compliant clients whose dogs are currently on another heartworm preventative. Current, compliant clients may be the most likely candidates to switch to ProHeart 6 since they’ve proven that they follow the directions of their veterinarians. If the client agrees to switch, administer the first ProHeart 6 dose(s) to their dog(s).
6. Encourage team members and veterinarians to find noncompliant clients, then educate them about the importance of heartworm disease and how to protect their dogs with ProHeart 6. Award prizes to those who speak with the most clients or engage the most new ProHeart 6 users.
7. Track achievements inside the clinic (perhaps use a progress tracker on a bulletin board or whiteboard) to build awareness and excitement among your team.
8. Incentivize dog owners who use ProHeart 6 to provide your clinic with testimonials of their experience with the product. They could post comments and other content on your clinic’s social communities in exchange for fun prizes.

## TALK TO DOG OWNERS

Start a conversation with clients about their heartworm disease prevention practices. It's important to ask a few questions at the start of any heartworm disease discussion:

“What’s your current heartworm preventative?”

“What’s been your experience giving monthly heartworm medication to your dog?”

“Do you sometimes forget or are you late giving a heartworm preventative to your dog?”

“What creative ideas do you use to remember to give your dog a heartworm preventative every month?”

### TALK TIPS

1. Recommend ProHeart 6 by touching on the benefits and convenience of it. Dog owners trust the veterinarian and healthcare team’s recommendations.
2. Make sure that dog owners understand the importance of year-round protection against heartworm disease. If need be, ask open-ended questions just to ensure they’re well aware of the risk.
3. Role-play with your healthcare team to help them confidently recommend ProHeart 6 to clients.
4. Prepare owners for starting puppies on ProHeart 6 when puppies reach 6 months old. Include ProHeart 6 in conversations about preventative protocols.
5. While the client is in the clinic for the first ProHeart 6 injection, schedule the next injection appointment before they leave. Encourage clients to mark their calendars and set up reminders for themselves.

### DOG OWNER TOUCH POINTS

Create a structured approach for heartworm disease prevention by thinking through four main touch points with dog owners:

#### **Touch Point 1, Receptionist:**

Checks the record for compliance. Inserts sticky note with last heartworm purchase date on the patient’s record. Gives a ProHeart 6 brochure to dog owner.

#### **Touch Point 2, Technician:**

Checks sticky note from receptionist. Educates the dog owner about ProHeart 6. Inquires about heartworm protection for the client’s dog.

#### **Touch Point 3, Veterinarian:**

Checks sticky note. Examines dog to ensure it is healthy. Recommends ProHeart 6. Reviews ProHeart 6 client information sheet with the client. Administers dose of ProHeart 6.

#### **Touch Point 4, Receptionist:**

Reinforces the benefits of heartworm protection. Schedules the next dose visit. Ensures that the dog owner sets up a calendar reminder.

## WHAT'S WORKED FOR OTHER CLINICS

We checked with other clinics to get their take on how they successfully implemented ProHeart 6. Here's what they had to say:

1. Simplify the heartworm preventative decision-making process by taking other heartworm preventatives off the shelf.
2. Offer a free or discounted heartworm test with ProHeart 6.
3. Price ProHeart 6 competitively with other heartworm preventatives. This can help increase demand and foster the client's use of ancillary services that can be provided when seeing the dog every six months.
4. Make the next six-month appointment before the dog owner leaves the practice. Emphasize the importance of the next appointment, and have the pet owner set up a reminder on his/her calendar or smartphone.
5. Remember, reminders will bring dogs back for a second dose. Here are some tips:
  - If they don't have an appointment, call dog owners one month before ProHeart 6 is due. When they have an appointment, call three to four days prior to their appointment to confirm.
  - Send an email two weeks before ProHeart 6 is due.
  - Send postcard reminders.
  - Use your clinic's Facebook page for reminders and education.
  - Use Vetstreet reminders.
  - Use various ProHeart 6 reminders from Zoetis. Talk to your Zoetis representative for more information.
  - Encourage dog owners to sign up for email, phone and text reminders here: [www.proheart6.com/SignUpForReminder.aspx](http://www.proheart6.com/SignUpForReminder.aspx).
  - Use magnets.
  - Use reminder stickers.
  - Enroll in the ProHeart 6 Owner Outreach Program.
6. Give a 10% discount or a free heartworm disease test if the dog owner prepays for the second dose. You will have a guaranteed visit in six months.
7. Send a "Congratulations: your dog is protected for six months" letter.
8. Include ProHeart 6 in wellness plans.
9. Offer a no-charge examination during the second ProHeart 6 injection.
10. Position ProHeart 6 as your only heartworm disease preventative for dogs 6 months or older.
11. Promote the convenience of ProHeart 6. Stress the ease of one injection two times a year as opposed to giving a preventative 12 times per year.
12. Increase awareness and keep ProHeart 6 top of mind via promotions like:
  - Create ProHeart 6 T-shirts or scrubs for your team
  - Display posters in the lobby and exam rooms
  - Create ProHeart 6 outdoor signs
  - Display ProHeart 6 banners or window clings on the clinic door
  - Create ProHeart 6 badges/buttons that your team can wear
  - Display ProHeart 6 dog owner brochures

**CONTACT YOUR ZOETIS  
REPRESENTATIVE OR GO TO  
PROHEART6DVM.COM FOR  
MORE INFORMATION.**

# ProHeart® 6

(moxidectin)

## Sustained Release Injectable for Dogs

### CAUTION

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

### DESCRIPTION

ProHeart 6 (moxidectin) Sustained Release Injectable 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. No other diluent should be used. A clear or translucent appearance of the vehicle is normal. Each mL of constituted drug product contains 3.4 mg moxidectin, 3.1% glyceryl tristearate, 2.4% hydroxypropyl methylcellulose, 0.87% sodium chloride, 0.17% methylparaben, 0.02% propylparaben and 0.001% butylated hydroxytoluene. Hydrochloric acid is used to adjust pH.

### PHARMACOLOGY

Moxidectin is a semi-synthetic methoxime derivative of nemadectin which is a fermentation product of *Streptomyces cyaneogriseus* subspecies nancyangenus. Moxidectin is a pentacyclic 16-membered lactone macrolide. Moxidectin has activity resulting in paralysis and death of affected parasites. The stage of the canine heartworm affected at 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. Following injection with ProHeart 6, peak moxidectin blood levels will be observed approximately 7-14 days after treatment. At the end of the six month dosing interval, residual drug concentrations are negligible. Accordingly, little or no drug accumulation is expected to occur with repeated administrations.

### 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*.

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

### DOSAGE AND ADMINISTRATION

Owners should be given the Client Information Sheet for ProHeart 6 to read before the drug is administered and should be advised to observe their dogs for potential drug toxicity described in the sheet.

**Frequency of Treatment:** ProHeart 6 prevents infection by *D. immitis* for six months. It should be administered within one month of the dog's first exposure to mosquitoes. Follow-up treatments may be given every six months if the dog has continued exposure to mosquitoes and if the dog continues to be healthy without weight loss. When replacing another heartworm preventive product, ProHeart 6 should be given within one month of the last dose of the former medication.

ProHeart 6 eliminates the larval and adult stages of *A. caninum* and *U. stenocephala* present at the time of treatment. However, persistent effectiveness has not been established for this indication. Re-infection with *A. caninum* and *U. stenocephala* may occur sooner than 6 months.

**Dose:** The recommended subcutaneous dose is 0.05 mL of the constituted suspension/kg body weight (0.0227 mL/lb.). This amount of suspension will provide 0.17 mg moxidectin/kg bodyweight (0.0773 mg/lb.). To ensure accurate dosing, calculate each dose based on the dog's weight at the time of treatment. Do not overdose growing puppies in anticipation of their expected adult weight. The following dosage chart may be used as a guide.

DOSAGE CHART					
Dog Wt.		Dose Volume	Dog Wt.		Dose Volume
lb	kg	mL/Dog	lb	kg	mL/Dog
11	5	0.25	77	35	1.75
22	10	0.50	88	40	2.00
33	15	0.75	99	45	2.25
44	20	1.00	110	50	2.50
55	25	1.25	121	55	2.75
66	30	1.50	132	60	3.00

**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 suspension/kg body weight 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 dorsum of the neck cranial to the scapula. No more than 3 mL should be administered in a single site. The location(s) of each injection (left or right side) should be noted so that prior injection sites can be identified and the next injection can be administered on the opposite side.

### INFORMATION FOR DOG OWNERS

Always provide Client Information Sheet and review with owners before administering ProHeart 6. 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, PRECAUTIONS and ADVERSE REACTIONS** 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.

### CONTRAINDICATIONS

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

### 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. If accidental ingestion occurs, contact a Poison Control Center or a physician immediately. The material safety data sheet (MSDS) contains more detailed occupational safety information.

### WARNINGS

ProHeart 6 should be administered with caution in dogs with pre-existing allergic disease, including food allergy, atopy, and flea allergy dermatitis. In some cases, anaphylactic reactions have resulted in liver disease and death. Anaphylactic and anaphylactoid reactions should be treated immediately with the same measures used to treat hypersensitivity reactions to vaccines and other injectable products.

Owners should be given the Client Information Sheet for ProHeart 6 to read before the drug is administered and should be advised to observe their dogs for potential drug toxicity described in the sheet.

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

### PRECAUTIONS

Caution should be used when administering ProHeart 6 concurrently with vaccinations. Adverse reactions, including anaphylaxis, have been reported following the concomitant use of ProHeart 6 and vaccinations (see **WARNINGS**).

Prior to administration of ProHeart 6, the health of the patient should be assessed by a thorough medical history, physical examination and diagnostic testing as indicated (see **WARNINGS**).

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

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

Caution should be used when administering ProHeart 6 to heartworm positive dogs (see **ADVERSE REACTIONS**).

Prior to administration of ProHeart 6, dogs should be tested for existing heartworm infections. Infected dogs should be treated to remove adult heartworms. ProHeart 6 is not effective against adult *D. immitis* and, while the number of circulating microfilariae may decrease following treatment, ProHeart 6 is not effective for microfilariae clearance.

### ADVERSE REACTIONS

In field studies, the following adverse reactions were observed in dogs treated with ProHeart 6: anaphylaxis, vomiting, diarrhea (with and without blood), listlessness, weight loss, seizures, injection site pruritus, and elevated body temperature. Dogs with clinically significant weight loss (>10%) were more likely to experience a severe adverse reaction.

In a laboratory effectiveness study, dogs with 4- and 6-month-old heartworm infections 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 (Rev. 2010)** The following adverse events are based on post-approval adverse drug experience reporting. 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 treated with ProHeart 6.

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

To report suspected adverse reactions, to obtain a Material Safety Data Sheet, or for technical assistance, call 1-888-963-8471.

For a complete listing of adverse reactions for moxidectin reported to the CVM see: <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductsSafetyInformation/ucm055394.htm>

### ANIMAL SAFETY

**General Safety:** ProHeart 6 has been administered to a wide variety of healthy dogs six months of age and older, including a wide variety of breeds, pregnant and lactating females, breeding males, and ivermectin-sensitive collies. In clinical studies, two geriatric dogs with a history of weight loss after the initial ProHeart 6 injection died within a month of the second 6 month injection. A third dog who was underweight for its age and breed and who had a history of congenital problems experienced lethargy following the initial injection of ProHeart 6. The dog never recovered and died 3 months later (see **WARNINGS**).

ProHeart 6 administered at 3 times the recommended dose in dogs with patent heartworm infections and up to 5 times the recommended dose in ivermectin-sensitive collies did not cause any adverse reactions. ProHeart 6 administered at 3 times the recommended dose did not adversely affect the reproductive performance of male or female dogs.

ProHeart 6 administered up to 5 times the recommended dose in 7-8 month old puppies did not cause any systemic adverse effects.

In well controlled clinical field studies, ProHeart 6 was used in conjunction with a variety of veterinary products including anthelmintics, antiparasitics, antibiotics, analgesics, steroids, non-steroidal anti-inflammatory drugs (NSAIDs), anesthetics and flea control products.

**Injection Site 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 and evaluations of the injection sites revealed no abnormalities.

In a laboratory safety study, ProHeart 6 was administered at 1, 3 and 5 times the recommended dose to 7-8 month old puppies. Injection sites were clipped to facilitate observation. Slight swelling/edema at the injection site was observed in some dogs from all treated groups. These injection site reactions appeared as quickly as 8 hours post injection and lasted up to 3 weeks. A three-year repeated injection study was conducted to evaluate the safety of up to 6 injections of ProHeart 6 administered at the recommended dose (0.17 mg/kg) every 6 months. Mild erythema and localized deep subcuticular thickening were seen in dogs that received four injections in the same area on the neck and in one dog that received two injections in the same area on the neck. Microscopic evaluation on the injection sites from all dogs 6 months after the last injection consistently showed mild granulomatous panniculitis with microvacuolation. The only adverse reaction seen that was not related to the injection site was weight loss in one dog.

Some dogs treated with ProHeart 6 in laboratory effectiveness studies developed transient, localized inflammatory injection site reactions. These injection site reactions were visible grossly for up to 3 weeks after injection. Histologically, well-defined granulomas were observed in some dogs at approximately 5 months after injection.

### CONSTITUTION PROCEDURES

The two-part ProHeart 6 product must be mixed at least 30 minutes prior to the intended time of use.

Items needed to constitute ProHeart 6:

- Microspheres
- Enclosed vent needle (25G)
- Vehicle
- Sterile 20 mL syringe for transfer
- Transfer needle (18G or 20G)



Constitution of the 20 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 17.0 mL of the unique vehicle from the vial. **There is more vehicle supplied than the 17.0 mL required.**
3. Insert the enclosed 25G vent needle into the microsphere vial.
4. Slowly transfer the vehicle into the microsphere vial through the stopper using the transfer needle and syringe.
5. Once the vehicle has been added, remove the vent and transfer needles from the microsphere vial. Discard unused vehicle and needles.
6. Shake the microsphere vial vigorously until a thoroughly mixed suspension is produced.
7. Record the time and date of mixing on the microsphere vial.
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 microspheres and vehicle will gradually separate on standing.
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.
11. Refrigerate the unused product. The constituted product remains stable for 4 weeks in a refrigerator. Avoid direct sunlight.

### 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 4 weeks stored under refrigeration at 2° to 8°C (36° to 46°F).

### HOW SUPPLIED

ProHeart 6 is available in the following three package sizes.

1. 1-Pack	2. 5-Pack	3. 10-Pack
20 mL vial product:	20 mL vial product:	20 mL vial product:
1 - 10% moxidectin sterile microspheres	5 - 10% moxidectin sterile microspheres	10 - 10% moxidectin sterile microspheres
- 598 mg/vial	- 598 mg/vial	- 598 mg/vial
1 - Sterile vehicle - 17 mL/vial	5 - Sterile vehicle - 17 mL/vial	10 - Sterile vehicle - 17 mL/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.

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