

Date of Approval: **MAY 23 2008**

# FREEDOM OF INFORMATION SUMMARY

## SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-189

PROHEART 6 Sustained Release Injectable for Dogs

(Moxidectin)

Dogs over 6 months of age

This supplement provides for the revision of the animal safety information in the warning, precaution, adverse reactions, and post-approval sections of the product labeling.

Sponsored by:

Fort Dodge Animal Health  
Division of Wyeth

2008-141-189

FOIS

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**I. GENERAL INFORMATION:**

- A. File Number:** NADA 141-189
- B. Sponsor:** Fort Dodge Animal Health  
Division of Wyeth  
800 Fifth St., NW.  
Fort Dodge, IA 50501
- Drug Labeler Code: 000856
- C. Proprietary Name(s):** PROHEART 6 Sustained Release Injectable for Dogs
- D. Established Name(s):** Moxidectin
- E. Pharmacological Category:** Antiparasitic
- F. Dosage Form(s):** Sterile Suspension
- G. Amount of Active Ingredient(s):** Each mL of constituted suspension contains 3.4 mg moxidectin.
- H. How Supplied:** ProHeart 6 consists of two separate vials. Vial 1 contains 10% moxidectin sterile microspheres and Vial 2 contains sterile vehicle for constitution. ProHeart 6 is available in two sizes:  
20 mL size (598 mg/vial moxidectin plus 17 mL/vial sterile vehicle)  
50 mL size (1,549 mg/vial moxidectin plus 44 mL/vial sterile vehicle)
- I. How Dispensed:** Rx
- J. Dosage(s):** The recommended subcutaneous dose is 0.05 mL of the constituted suspension/kg body weight (0.227 mL/lb). This amount of suspension will provide 0.17 mg moxidectin/kg body weight (0.0773 mg/lb).
- K. Route(s) of Administration:** Subcutaneous injection

- L. Species/Class(es):** Dogs over 6 months of age
- M. Indication(s):** 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.
- N. Effect(s) of Supplement:** This supplement provides for the revision of the animal safety information in the warning, precaution, adverse reactions, and post-approval sections of the product labeling.

## **II. EFFECTIVENESS:**

### **A. Dosage Characterization:**

This supplemental approval does not change the previously approved dosage. The Freedom of Information (FOI) Summary for the original approval of NADA 141-189 dated June 6, 2001, and a supplemental approval dated June 13, 2002, contain dosage characterization information for dogs over 6 months of age.

### **B. Substantial Evidence:**

CVM did not require effectiveness studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-289 dated June 6, 2001, and a supplemental approval dated June 13, 2002, contain a summary of studies that demonstrate effectiveness of the drug for dogs over 6 months of age.

## **III. TARGET ANIMAL SAFETY:**

CVM did not require target animal safety studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-189 dated June 6, 2001, and a supplemental approval dated June 13, 2002, contain a summary of target animal safety studies for dogs over 6 months of age.

## **IV. HUMAN FOOD SAFETY:**

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this NADA.

**V. USER SAFETY:**

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to PROHEART 6 Sustained Release Injectable for Dogs:

**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.

**VI. AGENCY CONCLUSIONS:**

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 514. The data demonstrate that PROHEART 6 Sustained Release Injectable for Dogs, when used according to the label, is safe and effective for use in dogs six months of age and older for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

**A. Marketing Status:**

This product may be dispensed only by or on the lawful order of a licensed veterinarian (Rx marketing status). Adequate directions for lay use cannot be written because professional expertise is required to properly administer the injection, provide adequate instructions for post treatment care, and to monitor the safe use of the product, including treatment of any adverse reactions.

**B. Exclusivity:**

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

**C. Supplemental Applications:**

This supplemental NADA did not require a reevaluation of the safety or effectiveness data in the original NADA (21 CFR 514.106(b)(2)).

**D. Patent Information:**

The sponsor did not submit any patent information with this application.

**VII. ATTACHMENTS:**

Labeling:

- a) Package Insert:
  - i) 20 mL Presentation
  - ii) 20 mL and 50 mL Presentation
  
- b) Client Information Sheets:
  - i) Back of Package Insert 20 mL Presentation (Code 3670G)
  - ii) Back of Package Insert 20 mL and 50 mL Presentation (Code 3671G)
  
- c) Vial Labeling:
  - i) 598 mg Moxidectin Sterile Microspheres
  - ii) 17 mL Sterile Vehicle
  - iii) 1549 mg Moxidectin Sterile Microspheres
  - iv) 44 mL Sterile Vehicle
  
- d) Carton Labeling:
  - i) Single Pack – 20 mL Presentation
  - ii) 5- Pack – 20 mL Presentation
  - iii) 10- Pack – 20 mL Presentation
  - iv) Single Pack – 50 mL Presentation

**FORT DODGE ANIMAL HEALTH**

Revision: 0  
 Expires: 05/01/05  
 Date: 08/24/05  
 Product ID: 26714  
 Reference #: 136315  
 Product Name: ProHeart 6  
 Trade Name: IMMOX  
 FDA Template: CGR  
 Dimensions:  
 Sheet: 2.12 x 9.0  
 Folded: 1.36 x 2.14  
 File Path: V:\9156714  
 : : 3576  
 PDF: 06/04/03 HAI  
 Rev Level: F

A. J. LANGRISH, VETERINARIAN  
 11500 W. 10th St. Ste. 100  
 Fort Dodge, SD 57520  
 (605) 773-3110

NADA 141-188, Approved by FDA

## ProHeart® 6 (moxidectin)

Sustained Release Injectable for Dogs

**CAUTION**

For oral (P.O.) use only. Do not use for injection.

**DESCRIPTION**  
 ProHeart 6 (moxidectin) Sustained Release Injectable consists of one capsule and one 10 mL syringe. The capsule contains 10% moxidectin and 90% polyethylene glycol (PEG) 3350. The syringe contains 10% moxidectin and 90% polyethylene glycol (PEG) 3350. The capsule and syringe are sterile and contain no preservatives.

**INDICATIONS**  
 Moxidectin is a semi-synthetic macrocyclic lactone of avermectins which is a potent antiparasitic agent against nematodes, cestodes, and arthropods. Moxidectin is a neurotoxic agent which causes paralysis and death of affected parasites. The drug is active against the following parasites: heartworm (Dirofilim immitis), lungworm (Oslerus rostratus), whipworm (Trichostrongylus axei), roundworm (Toxocara canis), hookworm (Uncinaria stenocephala), and ear mite (Otodectes cynotis). ProHeart 6 is indicated for the treatment of existing and future infections caused by these parasites.

**CONTRAINDICATIONS**  
 ProHeart 6 is contraindicated in animals previously found to be hypersensitive to it.

**WARNINGS**  
 Do not administer ProHeart 6 within 4 weeks of vaccination. Dogs with severe allergic reactions to any of the ingredients should not receive ProHeart 6. Do not administer ProHeart 6 to dogs with severe allergic reactions to any of the ingredients. Do not administer ProHeart 6 to dogs with severe allergic reactions to any of the ingredients. Do not administer ProHeart 6 to dogs with severe allergic reactions to any of the ingredients.

**DOSE CHART**

Sex	Age	Dose (mg)		Dose (mg)	Sex	Age	Dose (mg)	
		Initial	Subsequent				Initial	Subsequent
M	12 wks	1.0	0.5	1.0	F	12 wks	0.5	0.5
M	12 wks	1.0	0.5	1.0	F	12 wks	0.5	0.5
M	12 wks	1.0	0.5	1.0	F	12 wks	0.5	0.5
M	12 wks	1.0	0.5	1.0	F	12 wks	0.5	0.5
M	12 wks	1.0	0.5	1.0	F	12 wks	0.5	0.5
M	12 wks	1.0	0.5	1.0	F	12 wks	0.5	0.5

**Directions:** The two-part Sustained Release Injectable must be given to dogs 10-12 weeks of age. The capsule should be given to dogs 10-12 weeks of age. The syringe should be given to dogs 10-12 weeks of age. The capsule and syringe should be given to dogs 10-12 weeks of age. The capsule and syringe should be given to dogs 10-12 weeks of age.

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# 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. Vial 1 contains 10% moxidectin sterile microspheres and Vial 2 contains a specifically formulated sterile vehicle for constitution with Vial 1. 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 *nancyanogenus*. 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

**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 body weight (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.

### 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

**Do not administer ProHeart 6 within 1 month of vaccinations.** 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

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 (March 2008):** The following adverse reactions are based on voluntary post-approval drug experience reporting. The categories are listed in decreasing order of frequency by body system:

- General:** Anaphylaxis/toid reactions, depression/lethargy, anorexia, fever, weight loss.
- Gastrointestinal:** Vomiting (with and without blood), diarrhea (with and without blood), hypersalivation.
- Neurological:** Convulsions, ataxia, trembling, hind limb paresis
- Dermatological:** Urticaria, head/ facial edema, injection site pruritus/swelling, erythema multiforme.
- Hematological:** Immune-mediated hemolytic anemia, leukocytosis, immune-mediated thrombocytopenia
- Hepatic:** Elevated liver enzymes, hepatopathy, hypoproteinemia, hyperbilirubinemia.
- Respiratory:** Dyspnea, polypnea, coughing.

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**Post-Approval Experience (March 2008):** The following adverse reactions are based on voluntary post-approval drug experience reporting. The categories are listed in decreasing order of frequency by body system:

**General:** Anaphylaxis/toxic reactions, depression/lethargy, anorexia, fever, weight loss.

**Gastrointestinal:** Vomiting (with and without blood), diarrhea (with and without blood), hypersalivation.

**Neurological:** Convulsions, ataxia, trembling, hind limb paresis

**Dermatological:** Urticaria, head/face edema, injection site pruritus/swelling, erythema multiforme.

**Hematological:** Immune-mediated hemolytic anemia, leukocytosis, immune-mediated thrombocytopenia

**Hepatic:** Elevated liver enzymes, hepatopathy, hypoproteinemia, hyperbilirubinemia.

**Respiratory:** Dyspnea, polypnea, coughing.

Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm-positive dogs treated with ProHeart 6.

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

To report suspected adverse reactions or to obtain technical assistance, call (800) 533-8536.

#### 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 (vial 1)
- Enclosed vent needle (25G)
- Vehicle (vial 2)
- Sterile 20 mL syringe for transfer
- Transfer needle (18G or 20G)



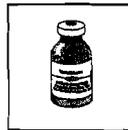
##### A. Constitution of the 20 mL vial product.

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.



##### B. Constitution of the 50 mL vial product.

Follow the same instructions as those for the 20 mL vial except that 44 mL of the unique vehicle should be transferred into the moxidectin microsphere vial.



#### 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 four package sizes.

1. **Large Single Twin Pack**  
NDC 0856-3670-50 – 50 mL vial product:  
1 - 10% moxidectin sterile microspheres - 1549 mg/vial  
1 - Sterile vehicle - 44 mL/vial
2. **Small Single Twin Pack**  
NDC 0856-3670-20 – 20 mL vial product:  
1 - 10% moxidectin sterile microspheres - 598 mg/vial  
1 - Sterile vehicle - 17 mL/vial
3. **5-Pack**  
NDC 0856-3670-25 – 20 mL vial product:  
5 - 10% moxidectin sterile microspheres - 598 mg/vial  
5 - Sterile vehicle - 17 mL/vial
4. **10-Pack**  
NDC 0856-3670-29 – 20 mL vial product:  
10 - 10% moxidectin sterile microspheres - 598 mg/vial  
10 - Sterile vehicle - 17 mL/vial

For customer service, product information or to obtain a copy of the MSDS, call (800) 533-8536.

U.S. Patent No. 4,916,154 and 6,340,671

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**Fort Dodge Animal Health**  
Fort Dodge, Iowa 50501 USA

## Client Information about ProHeart® 6 (moxidectin)

ProHeart 6 (pronounced "Pro-hart" "six")  
Generic name: moxidectin ("mox-ee-deck-tin")

This summary contains important information about ProHeart 6. You should read this information before your veterinarian administers ProHeart 6 to your dog and review it each time your dog is retreated. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about ProHeart 6.

### What is ProHeart 6 and why has my veterinarian prescribed ProHeart 6?

ProHeart 6 is an injectable parasiticide that is used in dogs six months of age and older to prevent heartworm disease (*Dirofilaria immitis*) continuously for six months and to treat common hookworm infections (*Ancylostoma caninum* and *Uncinaria stenocephala*).

### What should I discuss with my veterinarian before ProHeart 6 is prescribed?

Your veterinarian is your best resource for recommending appropriate medications for your dog. It is important to discuss your dog's health history with your veterinarian so he/she can decide if ProHeart 6 is right for your dog.

### Which dogs should not be treated with ProHeart 6?

ProHeart 6 should not be used in sick, debilitated or underweight animals. ProHeart 6 should be given with caution in dogs with pre-existing allergic disease, including previous vaccine reactions, food allergy, atopy, and flea allergy dermatitis. Dogs should be tested for heartworm disease prior to being treated with ProHeart 6. If your dog tests positive for adult heartworms, your veterinarian should treat the infection with an appropriate medication before administering ProHeart 6.

### What possible side effects of ProHeart 6 should I look for in my dog?

- Severe allergic reactions (anaphylaxis): facial swelling, itching, difficulty breathing, collapse
  - Lethargy (sluggishness), not eating or losing interest in food, any change in activity level
  - Seizures
  - Vomiting and/or diarrhea (with and without blood)
  - Weight loss
  - Pale gums, increased thirst or urination, weakness, bleeding, bruising
- If you notice any of these side effects or have any concerns about your dog, please contact your veterinarian as soon as possible.

### Can ProHeart 6 be given with other medicines?

In well-controlled clinical studies, ProHeart 6 was used safely in dogs receiving other veterinary products such as anthelmintics, antiparasitics, antibiotics, analgesics, steroids, non-steroidal anti-inflammatory drugs (NSAIDs), anesthetics, and flea control products. ProHeart 6 should not be given within one month of your dog being vaccinated. Tell your veterinarian about all medicines you have given your dog in the past, and any medicines that you are planning to use with ProHeart 6.

### How long will ProHeart 6 remain in the body?

Several studies have shown that by the end of the six-month treatment period, the amount of ProHeart 6 remaining in the body is too small to measure. An additional study demonstrated that after four consecutive treatments there was no accumulation of ProHeart 6 over time.

### What else should I know about ProHeart 6?

This sheet provides a summary of information about ProHeart 6. If you have any questions or concerns about ProHeart 6, talk to your veterinarian.

Read the package insert for more information.

To obtain additional information visit the website at [www.proheart6.com](http://www.proheart6.com), or call 1-877-6PROHEART (1-877-677-6432).

Fort Dodge Animal Health  
Fort Dodge, Iowa 50501 USA

# Client Information about ProHeart® 6 (moxidectin)

ProHeart 6 (pronounced “Pro-hart” “six”)  
Generic name: moxidectin (“mox-ee-deck-tin”)

This summary contains important information about ProHeart 6. You should read this information before your veterinarian administers ProHeart 6 to your dog and review it each time your dog is retreated. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about ProHeart 6.

## What is ProHeart 6 and why has my veterinarian prescribed ProHeart 6?

ProHeart 6 is an injectable parasiticide that is used in dogs six months of age and older to prevent heartworm disease (*Dirofilaria immitis*) continuously for six months and to treat common hookworm infections (*Ancylostoma caninum* and *Uncinaria stenocephala*).

## What should I discuss with my veterinarian before ProHeart 6 is prescribed?

Your veterinarian is your best resource for recommending appropriate medications for your dog. It is important to discuss your dog’s health history with your veterinarian so he/she can decide if ProHeart 6 is right for your dog.

## Which dogs should not be treated with ProHeart 6?

ProHeart 6 should not be used in sick, debilitated or underweight animals. ProHeart 6 should be given with caution in dogs with pre-existing allergic disease, including previous vaccine reactions, food allergy, atopy, and flea allergy dermatitis. Dogs should be tested for heartworm disease prior to being treated with ProHeart 6. If your dog tests positive for adult heartworms, your veterinarian should treat the infection with an appropriate medication before administering ProHeart 6.

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- Severe allergic reactions (anaphylaxis): facial swelling, itching, difficulty breathing, collapse
  - Lethargy (sluggishness), not eating or losing interest in food, any change in activity level
  - Seizures
  - Vomiting and/or diarrhea (with and without blood)
  - Weight loss
  - Pale gums, increased thirst or urination, weakness, bleeding, bruising
- **If you notice any of these side effects or have any concerns about your dog, please contact your veterinarian as soon as possible.**

## Can ProHeart 6 be given with other medicines?

In well-controlled clinical studies, ProHeart 6 was used safely in dogs receiving other veterinary products such as anthelmintics, antiparasitics, antibiotics, analgesics, steroids, non-steroidal anti-inflammatory drugs (NSAIDs), anesthetics, and flea control products. ProHeart 6 should not be given within one month of your dog being vaccinated. Tell your veterinarian about all medicines you have given your dog in the past, and any medicines that you are planning to use with ProHeart 6.

## How long will ProHeart 6 remain in the body?

Several studies have shown that by the end of the six-month treatment period, the amount of ProHeart 6 remaining in the body is too small to measure. An additional study demonstrated that after four consecutive treatments there was no accumulation of ProHeart 6 over time.

## What else should I know about ProHeart 6?

This sheet provides a summary of information about ProHeart 6. If you have any questions or concerns about ProHeart 6, talk to your veterinarian.

- Pale gums, increased thirst or urination, weakness, bleeding, bruising
- **If you notice any of these side effects or have any concerns about your dog, please contact your veterinarian as soon as possible.**

### **Can ProHeart 6 be given with other medicines?**

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### **What else should I know about ProHeart 6?**

This sheet provides a summary of information about ProHeart 6. If you have any questions or concerns about ProHeart 6, talk to your veterinarian.

Read the package insert for more information.

To obtain additional information visit the website at [www.proheart6.com](http://www.proheart6.com), or call 1-877-6PROHEART (1-877-677-6432).

**Fort Dodge Animal Health**  
**Fort Dodge, Iowa 50501 USA**

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Revised April 2008

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## Client Information about ProHeart® 6 (moxidectin)

ProHeart 6 (pronounced "Pro-hart" "six")  
Generic name: moxidectin ("mox-ee-deck-tin")

This summary contains important information about ProHeart 6. You should read this information before your veterinarian administers ProHeart 6 to your dog and review it each time your dog is retreated. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about ProHeart 6.

### What is ProHeart 6 and why has my veterinarian prescribed ProHeart 6?

ProHeart 6 is an injectable parasiticide that is used in dogs six months of age and older to prevent heartworm disease (*Dirofilaria immitis*) continuously for six months and to treat common hookworm infections (*Ancylostoma caninum* and *Uncinaria stenocephala*).

### What should I discuss with my veterinarian before ProHeart 6 is prescribed?

Your veterinarian is your best resource for recommending appropriate medications for your dog. It is important to discuss your dog's health history with your veterinarian so he/she can decide if ProHeart 6 is right for your dog.

### Which dogs should not be treated with ProHeart 6?

ProHeart 6 should not be used in sick, debilitated or underweight animals. ProHeart 6 should be given with caution in dogs with pre-existing allergic disease, including previous vaccine reactions, food allergy, atopy, and flea allergy dermatitis. Dogs should be tested for heartworm disease prior to being treated with ProHeart 6. If your dog tests positive for adult heartworms, your veterinarian should treat the infection with an appropriate medication before administering ProHeart 6.

### What possible side effects of ProHeart 6 should I look for in my dog?

- Severe allergic reactions (anaphylaxis): facial swelling, itching, difficulty breathing, collapse
  - Lethargy (sluggishness), not eating or losing interest in food, any change in activity level
  - Seizures
  - Vomiting and/or diarrhea (with and without blood)
  - Weight loss
  - Pale gums, increased thirst or urination, weakness, bleeding, bruising
- If you notice any of these side effects or have any concerns about your dog, please contact your veterinarian as soon as possible.

### Can ProHeart 6 be given with other medicines?

In well-controlled clinical studies, ProHeart 6 was used safely in dogs receiving other veterinary products such as anthelmintics, antiparasitics, antibiotics, analgesics, steroids, non-steroidal anti-inflammatory drugs (NSAIDs), anesthetics, and flea control products. ProHeart 6 should not be given within one month of your dog being vaccinated. Tell your veterinarian about all medicines you have given your dog in the past, and any medicines that you are planning to use with ProHeart 6.

### How long will ProHeart 6 remain in the body?

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### What else should I know about ProHeart 6?

This sheet provides a summary of information about ProHeart 6. If you have any questions or concerns about ProHeart 6, talk to your veterinarian.

Read the package insert for more information.

To obtain additional information visit the website at [www.proheart6.com](http://www.proheart6.com), or call 1-877-6PROHEART (1-877-677-6432).

## **Client Information about ProHeart® 6 (moxidectin)**

ProHeart 6 (pronounced "Pro-hart" "six")  
Generic name: moxidectin ("mox-ee-deck-tin")

This summary contains important information about ProHeart 6. You should read this information before your veterinarian administers ProHeart 6 to your dog and review it each time your dog is retreated. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about ProHeart 6.

### **What is ProHeart 6 and why has my veterinarian prescribed ProHeart 6?**

ProHeart 6 is an injectable parasiticide that is used in dogs six months of age and older to prevent heartworm disease (*Dirofilaria immitis*) continuously for six months and to treat common hookworm infections (*Ancylostoma caninum* and *Uncinaria stenocephala*).

### **What should I discuss with my veterinarian before ProHeart 6 is prescribed?**

Your veterinarian is your best resource for recommending appropriate medications for your dog. It is important to discuss your dog's health history with your veterinarian so he/she can decide if ProHeart 6 is right for your dog.

### **Which dogs should not be treated with ProHeart 6?**

ProHeart 6 should not be used in sick, debilitated or underweight animals. ProHeart 6 should be given with caution in dogs with pre-existing allergic disease, including previous vaccine reactions, food allergy, atopy, and flea allergy dermatitis. Dogs should be tested for heartworm disease prior to being treated with ProHeart 6. If your dog tests positive for adult heartworms, your veterinarian should treat the infection with an appropriate medication before administering ProHeart 6.

### **What possible side effects of ProHeart 6 should I look for in my dog?**

- Severe allergic reactions (anaphylaxis): facial swelling, itching, difficulty breathing, collapse
  - Lethargy (sluggishness), not eating or losing interest in food, any change in activity level
  - Seizures
  - Vomiting and/or diarrhea (with and without blood)
  - Weight loss
  - Pale gums, increased thirst or urination, weakness, bleeding, bruising
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  - Seizures
  - Vomiting and/or diarrhea (with and without blood)
  - Weight loss
  - Pale gums, increased thirst or urination, weakness, bleeding, bruising
- **If you notice any of these side effects or have any concerns about your dog, please contact your veterinarian as soon as possible.**

### **Can ProHeart 6 be given with other medicines?**

In well-controlled clinical studies, ProHeart 6 was used safely in dogs receiving other veterinary products such as anthelmintics, antiparasitics, antibiotics, analgesics, steroids, non-steroidal anti-inflammatory drugs (NSAIDs), anesthetics, and flea control products. ProHeart 6 should not be given within one month of your dog being vaccinated. Tell your veterinarian about all medicines you have given your dog in the past, and any medicines that you are planning to use with ProHeart 6.

### **How long will ProHeart 6 remain in the body?**

Several studies have shown that by the end of the six-month treatment period, the amount of ProHeart 6 remaining in the body is too small to measure. An additional study demonstrated that after four consecutive treatments there was no accumulation of ProHeart 6 over time.

### **What else should I know about ProHeart 6?**

This sheet provides a summary of information about ProHeart 6. If you have any questions or concerns about ProHeart 6, talk to your veterinarian.

Read the package insert for more information.

To obtain additional information visit the website at [www.proheart6.com](http://www.proheart6.com), or call 1-877-6PROHEART (1-877-677-6432).

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NDC 0856-3670-20

REF 60002

# ProHeart<sup>®</sup>6 (moxidectin)

Sustained Release Injectable for Dogs  
10% moxidectin sterile microspheres

598 mg

To be constituted with 17 mL ProHeart 6 vehicle.

**CAUTION:** Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.  
NADA 141-189. Approved by FDA

ProHeart 6 is indicated for use in dogs six months of age and older for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

The product must be mixed at least 30 minutes prior to the intended time of use. The recommended subcutaneous dose is 0.05 mL of the constituted suspension/kg body weight (0.0227 mL/lb).

**Read accompanying package insert carefully before use.**

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).

U.S. Patent No. 4,916,154 and 6,340,671

Fort Dodge Animal Health  
Fort Dodge, Iowa 50501 USA

Date/time  
of constitution:

Lot

Exp.

31-73C

NDC 0856-3670-20

08720232

# ProHeart<sup>®</sup>6 (moxidectin)

Sustained Release Injectable for Dogs  
Sterile Vehicle  
17 mL

To be used to constitute moxidectin microspheres.  
**CAUTION:** Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.  
NADA 141-189, Approved by FDA

ProHeart 6 is indicated for use in dogs six months of age and older for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

There is more vehicle supplied than required for constitution.

**Read accompanying package insert carefully before use.**

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).

U.S. Patent No. 4,916,154 and 6,340,671

**Fort Dodge Animal Health**  
Fort Dodge, Iowa 50501 USA

Lot  
Exp.

*Johnson*

3163C

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**FORT DODGE ANIMAL HEALTH**

Revision . . . . . 1  
 Operator . . . . . HAL  
 Date . . . . . 06Mar08  
 Product ID# . . . . . 3675B  
 Resource # . . . . . L3675  
 Product Name . . . . . ProHeart 6  
 Type/Size . . . . . Label/1549mg

FDAA Template . . . . . 105  
 Template Dim. . . . . 13/16" x 4 1/4"  
 File Path . . . . . \1\PF\3675B\3675B  
 PDF . . . . . 06Mar08 hal  
 Rev Level . . . . . E

ALL ELECTRONIC ARTWORK IS THE PROPERTY OF, AND MUST BE RETURNED TO FORT DODGE ANIMAL HEALTH.

NDC 0856-3670-50  
KAY/VAWAG

**ProHeart<sup>6</sup>**  
(moxidectin)  
Sustained Release Injectable for Dogs  
10% moxidectin eluting subcutaneous

**1549 mg**  
To be constituted with 44 mL ProHeart 6 vehicle.  
**CAUTION:** Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.  
NADA 141-189, Approved by FDA

ProHeart 6 is indicated for use in dogs six months of age and older for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of existing heartworm disease and lungworm (Pneumonyssoides caninum) and ear mite (Otodectes cheylei) infestations.  
This product must be mixed at least 30 minutes prior to the intended time of use.  
The recommended subcutaneous dose is 0.05 mL of the constituted suspension/kg body weight (0.0227 mL/lb.).  
Read accompanying package insert carefully before use.  
Store 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).  
U.S. Patent No. 4,976,154 and 6,340,671  
Fort Dodge Animal Health  
Fort Dodge, Iowa 50501 USA



303675 10

Exp.  
Lot

Date/Time  
of constitution:

FORT DODGE  
ANIMAL HEALTH

FORT DODGE

Revision . . . . . 1  
Operator . . . . . HAL  
Date . . . . . 06Mar08  
Product ID# . . . . . 3675B  
Resource # . . . . . L3675  
Product Name . . . . . ProHeart 6  
Type/Size . . . . . Label/1549mg

FDHA Template . . . 105  
Template Dim. . . . . 1 3/8" x 4 1/4"  
File Path . . . . . V1/PF/3675B/3675B  
PDF . . . . . 06Mar08 hal  
Rev Level . . . . . B

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ALL ELECTRONIC ARTWORK IS THE PROPERTY OF, AND MUST BE RETURNED TO FORT DODGE ANIMAL HEALTH.

NDC 0856-3670-50

FORT DODGE

ProHeart<sup>®</sup> 6  
(moxidectin)

Sustained Release Injectable for Dogs  
10% moxidectin sterile microspheres

1549 mg

To be constituted with 44 mL ProHeart 6 vehicle.

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

NADA 141-189, Approved by FDA

ProHeart 6 is indicated for use in dogs six months of age and older for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

The product must be mixed at least 30 minutes prior to the intended time of use.

The recommended subcutaneous dose is 0.05 mL of the constituted suspension/kg body weight (0.0227 mL/lb.).

**Read accompanying package insert carefully before use.**

Store 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).

U.S. Patent No. 4,916,154 and 6,340,671

**Fort Dodge Animal Health**  
**Fort Dodge, Iowa 50501 USA**



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30367510

Date/Time  
of constitution:

Lot  
Exp.

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**WYETH RED**

**FORT DODGE**  
**ANIMAL HEALTH**

Revision . . . . . 2  
Operator . . . . . Ish  
Date . . . . . 22Jun06  
Product ID# . . . . . 3685B  
Resource # . . . . . L3685  
Product Name . . . . . ProHeart 6  
Type/Size . . . . . Label / 44 mL

FDAH Template . . . 110  
Template Dim. . . . 1-3/8" x 4-1/4"  
File Path . . . . . V1/PF/3685B/  
3685B  
PDF . . . . . 22Jun06 Ish  
Rev Level . . . . . B

ALL ELECTRONIC ARTWORK IS THE PROPERTY OF, AND MUST BE RETURNED TO FORT DODGE ANIMAL HEALTH.

30368510

NDC 0956-3870-50  
**ProHeart6**  
(moxidectin)  
Sterile Solution  
44 mL  
To be used in conjunction with ivermectin  
in ophthalmics.  
**CAUTION:** Federal (U.S.A.) law restricts  
this drug to use by or on the order of  
a licensed veterinarian.  
NADA 141-183, Approved by FDA

ProHeart 6 is indicated for use in dogs six months of age and older for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of existing larval and adult heartworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.  
There is more weight supplied than required for constitution.  
Retail accompanying package insert carefully before use.  
Store 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).  
U.S. Patent No. 4,916,154 and 6,340,671  
**Fort Dodge Animal Health**  
Fort Dodge, Iowa USA



**FORT DODGE**

**FORT DODGE  
ANIMAL HEALTH**

Revision . . . . . 2  
Operator . . . . . lsh  
Date . . . . . 22Jun06  
Product ID# . . . . 3685B  
Resource # . . . . L3685  
Product Name . . ProHeart 6  
Type/Size . . . . . Label / 44 mL

FDAH Template . . 110  
Template Dim. . . 1-3/8" x 4-1/4"  
File Path . . . . . V1/PF/3685B/  
3685B  
PDF . . . . . 22Jun06 lsh  
Rev Level . . . . . B

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**WYETH RED**

ALL ELECTRONIC ARTWORK IS THE PROPERTY OF, AND MUST BE RETURNED TO FORT DODGE ANIMAL HEALTH.

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NDC 0856-3670-50

**FORT DODGE**

**ProHeart® 6**  
(moxidectin)

**Sustained Release Injectable for Dogs**  
**Sterile Vehicle**

**44 mL**

To be used to constitute moxidectin  
microspheres.

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

NADA 141-189, Approved by FDA

ProHeart 6 is indicated for use in dogs six months of age and older for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

There is more vehicle supplied than required for constitution.

**Read accompanying package insert carefully before use.**

Store 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).

U.S. Patent No. 4,916,154 and 6,340,671

**Fort Dodge Animal Health**  
**Fort Dodge, Iowa 50501 USA**

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**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.

**STORAGE:** 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).

U.S. Patent No. 4,916,154 and  
6,340,671

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NDC 0856-3670-20



# ProHeart<sup>®</sup> 6 (moxidectin)

**Sustained Release Injectable for Dogs**

1 Vial of Moxidectin Sterile Microspheres 598 mg  
1 Vial of Sterile Vehicle 17 mL  
1 Vent Needle

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

**Read accompanying package insert carefully before use.**

**Fort Dodge Animal Health**  
**Fort Dodge, Iowa 50501 USA**  
NADA 141-189, Approved by FDA

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

**DESCRIPTION:** ProHeart 6 consists of two separate vials. Vial 1 contains 10% moxidectin sterile microspheres and Vial 2 contains a specifically formulated sterile vehicle for constitution with Vial 1. 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.

**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 body weight (0.0773 mg/lb.).

**WARNINGS:** with caution  
In some cases  
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vaccines and

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and should  
administer f**

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ProHeart 6:  
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infections.

**Post-Approv  
drug experie**

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**Gastro**  
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**Neuro**  
**Dermat**  
**Hemat**  
**Hepati**  
**Respiri**

Cardiopulmo  
ProHeart 6. I  
To report su:

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00668

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

**DESCRIPTION:** ProHeart 6 consists of two separate vials. Vial 1 contains 10% moxidectin sterile microspheres and Vial 2 contains a specifically formulated sterile vehicle for constitution with Vial 1. 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.

**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 body weight (0.0773 mg/lb.).

**WARNINGS:** Do not administer ProHeart 6 within 1 month of vaccinations. 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:** 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 (March 2008):** The following adverse reactions are based on voluntary post-approval drug experience reporting. The categories are listed in decreasing order of frequency by body system:

**General:** Anaphylaxis/toxic reactions, depression/lethargy, anorexia, fever, weight loss.

**Gastrointestinal:** Vomiting (with and without blood), diarrhea (with and without blood), hypersalivation.

**Neurological:** Convulsions, ataxia, trembling, hind limb paresis

**Dermatological:** Urticaria, head/facial edema, injection site pruritus/swelling, erythema multiforme.

**Hematological:** Immune-mediated hemolytic anemia, leukocytosis, immune-mediated thrombocytopenia

**Hepatic:** Elevated liver enzymes, hepatopathy, hypoproteinemia, hyperbilirubinemia.

**Respiratory:** Dyspnea, polypnea, coughing.

Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm-positive dogs treated with ProHeart 6. In rare situations, death has been reported as an outcome of the adverse events listed above.

To report suspected adverse reactions or to obtain technical assistance, call (800) 533-8536.

# ProHeart® 6

(moxidectin)

Sustained Release Injectable for Dogs

USE VENT NEEDLE TO CONSTITUTE

**INDICATIONS:** ProHeart 6 is indicated for use in dogs six months of age and older for the prevention of heartworm disease caused by *Dirofilara immitis* (microfilariae) infections.

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

**STORAGE:** Store 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).

U.S. Patent No. 4,916,154 and 6,340,671

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To report suspected adverse reactions or to obtain technical assistance, call (800) 533-0232.

Contraindications: ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6. ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6. ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6.

Warnings: ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6. ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6.

Precautions: ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6. ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6.

Adverse Reactions: ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6. ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6.

How to Administer: ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6. ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6.

How to Store: ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6. ProHeart 6 should not be administered to dogs with known hypersensitivity to any of the ingredients of ProHeart 6.

**ProHeart® 6**  
(moxidectin)

1 Vial of Moxidectin Sterile Microspheres 1549 mg  
1 Vial of Sterile Vehicle 44 mL  
1 Vent Needle

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

Read accompanying package insert carefully before use.

Fort Dodge Animal Health  
Fort Dodge, Iowa 50501 USA  
NADA 141-189, Approved by FDA

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

**DESCRIPTION:** ProHeart 6 consists of two separate vials. Vial 1 contains 70% moxidectin sterile microspheres and Vial 2 contains a specially formulated sterile vehicle for constitution with Vial 1. No other diluent should be used. A clear normal appearance of the vehicle is expected. Each mL of constituted drug product contains 3.4 mg moxidectin, 2.4% glyceryl triacetate, 0.87% hydroxypropyl methylcellulose, 0.87% sodium chloride, 0.17% methylparaben, 0.02% propylparaben and 0.001% dibutyl hydroxytoluene. Hydrochloric acid is used to adjust pH.

**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 body weight (0.0773 mg/lb).

Revision	..... 2
Operator	..... HAJ
Date	..... 06/26/08
Product ID#	..... 3676F
Resource #	..... 9735
Product Name	..... ProHeart 6
Type/Size	..... Carton
FORT DODGE ANIMAL HEALTH 2008	
FOAM Template	..... 777
Template Dim.	..... 377x277x377
File Path	..... V1/P/3676F/6267SR
PDF	..... 06/26/08
Rev Level	..... F

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Fort Dodge Animal Health

**WARNINGS:** Do not administer ProHeart 6 within 1 month of vaccinations. 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.

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**Hepatic:** Elevated liver enzymes, hepatopathy, hypoproteinemia, hyperbilirubinemia.

**Respiratory:** Dyspnea, polypnea, coughing.

Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm-positive dogs treated with ProHeart 6. In rare situations, death has been reported as an outcome of the adverse events listed above.

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

**STORAGE:** Store 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).

U.S. Patent No. 4,916,154 and  
6,340,671

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1 Vial

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FORT DODGE ANIMAL HEALTH

# ProHeart<sup>®</sup> 6 (moxidectin)

1 Vial of Moxidectin Sterile Microspheres 1549 mg  
1 Vial of Sterile Vehicle 44 mL  
1 Vent Needle

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

**Read accompanying package insert carefully before use.**

Fort Dodge Animal Health  
Fort Dodge, Iowa 50501 USA  
NADA 141-189, Approved by FDA

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**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 body weight (0.0773 mg/lb.).