PROHEART 12- moxidectin
Zoetis Inc.

ProHeart® 12 (moxidectin)
For Extended-Release Injectable Suspension for Dogs

CAUTION

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

DESCRIPTION

ProHeart 12 (moxidectin) for extended-release injectable suspension consists of two separate vials: one vial contains 10% moxidectin sterile microspheres; and the second vial contains a specifically formulated sterile vehicle for constitution with the microspheres. A clear or translucent appearance of the vehicle is normal. Each mL of constituted drug product contains 10 mg moxidectin, 9% glyceryl tristearate, 2.25% hydroxypropyl methylcellulose, 0.81% sodium chloride, 0.16% methylparaben, 0.02% propylparaben and 0.004% butylated hydroxytoluene. Hydrochloric acid is used to adjust pH. The constituted product may appear as a hazy to milky suspension.

INDICATIONS

ProHeart 12 is indicated for use in dogs 12 months of age and older for the prevention of heartworm disease caused by *Dirofilaria immitis* for 12 months.
ProHeart 12 is indicated for the treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

DOSAGE AND ADMINISTRATION

Always provide Client Information Sheet and review with owners before administering ProHeart 12. The owner should be advised to observe their dog for adverse drug events including those described on the sheet. The Client Information Sheet is attached to this package insert and available online at http://www.proheart12.com for reprinting to provide to the owner.

Frequency of Treatment:

ProHeart 12 prevents the development of heartworm disease caused by *D. immitis* for 12 months. For dogs not previously on heartworm preventive or having lapsed beyond 12 months of a prior ProHeart 12 dose, the product should be given within 1 month of exposure to mosquitoes. Follow-up treatments may be given every 12 months, if the dog continues to be healthy and without weight loss, to provide continuous year-round protection. When replacing a monthly heartworm preventive product, ProHeart 12 should be given within one month of the last dose of the former medication to avoid a gap in protection.

ProHeart 12 eliminates the larval and adult stages of *A. caninum* and *U. stenocephala* present at the time of treatment. Re-infection with *A. caninum* and *U. stenocephala* may occur sooner than 12 months.

Dose:

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

following table provides a guide for weight specific dose volumes.

Table 1: Dosage Guide

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

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

Injection Technique:

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

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

Using aseptic technique, inject the product subcutaneously in the left or right side of the 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.

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 http://www.fda.gov/AnimalVeterinary/SafetyHealth.

Client Information Sheet

ProHeart 12

(moxidectin)

Review this information with your veterinarian each time your dog receives ProHeart 12. When your veterinarian prescribes medicine for your dog, it's sometimes hard to remember all the information discussed during the visit. This sheet is provided as a summary, but if you have any additional questions you should speak with your veterinarian.

What is ProHeart 12?
ProHeart 12 is a medication that prevents heartworm disease in dogs 12 months of age and older. Your veterinarian gives it to your dog via an injection and it protects your dog from developing heartworm disease for 12 full months. ProHeart 12 also treats common hookworm infections your dog may have at the time of injection.

What should I discuss with my veterinarian before using ProHeart 12?

• **General health** – ProHeart 12 should only be given to healthy dogs.
• **Changes in behavior or health,** including weight loss.
• **Allergies** – Past or present, uncontrolled allergies, including food, flea or skin allergies.
• **Past problems with or reactions to vaccines or medications**.
• **Current medications, supplements or special diets,** including those you can get without a prescription.

What is heartworm disease and how can my dog get it?
Heartworm disease is a serious, potentially fatal illness where worms grow in a dog's heart and lungs. Mosquitoes spread heartworm disease when they bite a dog. A single bite from an infected mosquito can put your dog at risk for developing heartworm disease.

What are hookworms and how could my dog get them?
Hookworms are common parasites that can live in a dog's intestines. Your dog can get hookworms by eating hookworm larvae (young hookworms) that may be in the dirt or they can get hookworms through skin contact.

What possible ProHeart 12 side effects could happen to my dog?
It is important to contact your veterinarian if you observe any signs of illness in your dog. Severe reactions require emergency treatment by your veterinarian. Watch your dog for the following possible signs of illness:
• **Allergic reactions** - Allergic symptoms such as swelling of the face, itching, hives and/or inflamed skin. Allergic reactions may occur when ProHeart 12 is given alone or with vaccines. Some allergic reactions can be severe, such as difficulty breathing or collapse.

• **Vomiting and/or diarrhea** - Either with or without blood.
• **Seizures**
• **Change in your dog's appetite or activity level**

Most reactions occur within the first 24 hours of receiving ProHeart 12; severe allergic reactions may occur in the first two hours.

IF YOU NOTICE ANY SIGNS OF ILLNESS, OR ANYTHING OUT OF THE ORDINARY AFTER YOUR DOG RECEIVES PROHEART 12, CONTACT YOUR VETERINARIAN IMMEDIATELY.

In some cases, these events may be serious and may cause death.

If you have any questions about ProHeart 12, talk to your veterinarian.

[Veterinarian: Please place contact information below]
Practice Name:
Vet Name:
Phone:
To obtain additional information, visit ProHeart12.com or call 1-888-963-8471.
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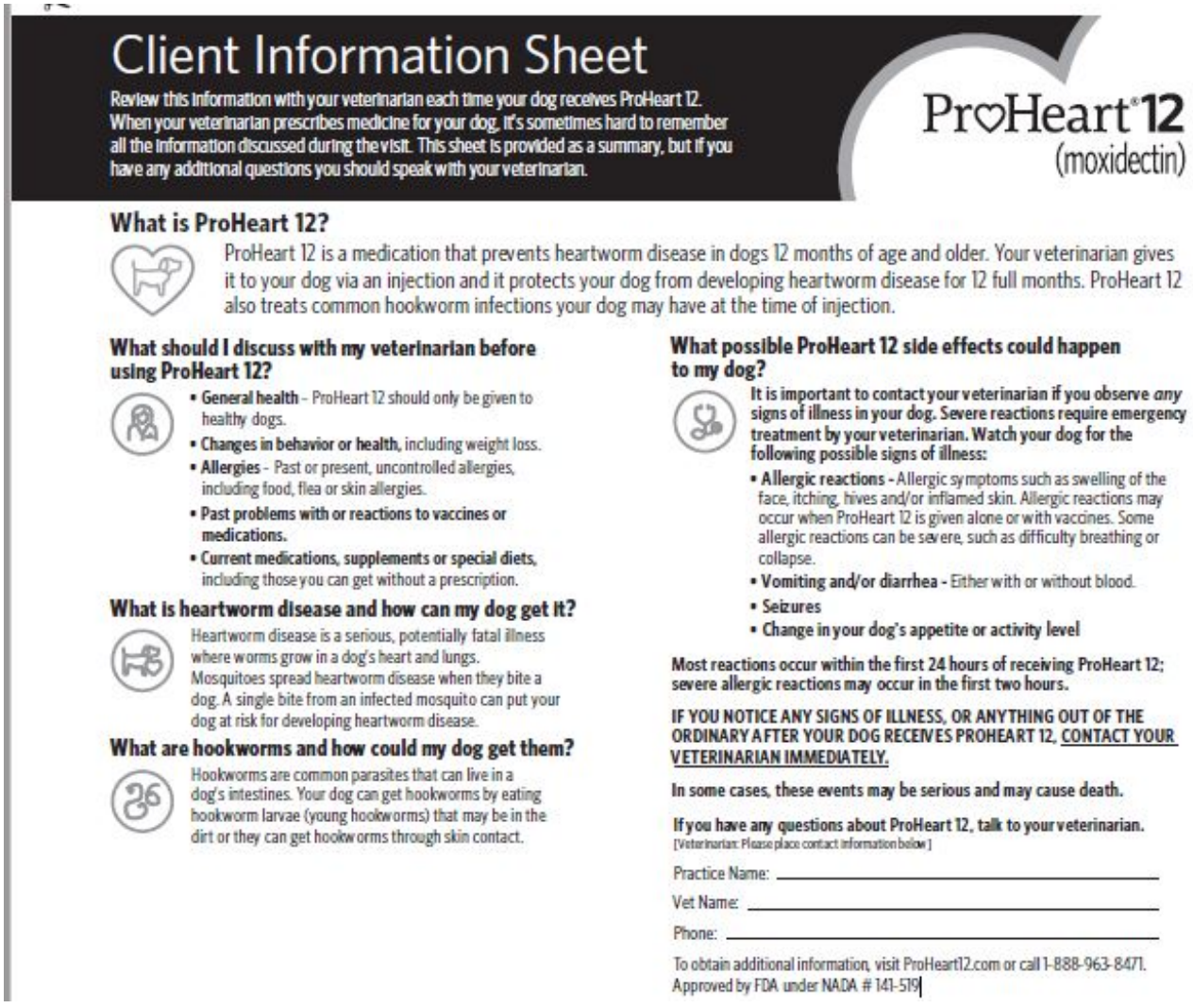

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If you have any questions about ProHeart 12, talk to your veterinarian.
[Veterinarian: Please place contact information below]

Practice Name: _____
Vet Name: _____
Phone: _____

To obtain additional information, visit ProHeart12.com or call 1-888-963-8471.
Approved by FDA under NADA # 141-519

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.

CLINICAL PHARMACOLOGY

Moxidectin is a semi-synthetic methoxime derivative of nemadectin which is a fermentation product of *Streptomyces cyaneogriseus* subspecies *noncyanogenus*. 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 0.5 mg/kg (0.23 mg/lb) is the tissue larval stage. The larval and adult stages of the canine hookworms, *A. caninum* and *U. stenocephala*, are susceptible.

Following injection with ProHeart 12, peak moxidectin blood levels will be observed approximately 7-14 days after treatment. At the end of the 12-month dosing interval, residual drug plasma concentrations are negligible. Accordingly, little or no drug accumulation is expected to occur with repeated administrations.

EFFECTIVENESS

Prevention of Heartworm:
In two separate well-controlled laboratory studies, ProHeart 12 administered at a dose of 0.5 mg/kg (0.23 mg/lb), demonstrated 100% effectiveness in preventing the development of *D. immitis* in dogs inoculated with infective larvae 365 days after treatment.

In a well-controlled 605-day US field study, two doses of ProHeart 12 were administered subcutaneously at a dosage of 0.5 mg/kg (0.23 mg/lb), 12 months apart. A total of 235, 226 and 222 ProHeart 12-treated dogs completed the heartworm testing (adult heartworm antigen and microfilariae) on Days 365, 480 and 605, respectively. None of these dogs tested positive for heartworm on any of the test days.

Treatment of Existing Larval and Adult Hookworms:
Seven well-controlled laboratory studies conducted with moxidectin microspheres at a dose of 0.17 mg/kg confirm the effectiveness against natural infections and induced infections of larval and adult *A. caninum* and *U. stenocephala*. All studies demonstrated ≥ 90% effectiveness against the respective hookworm species.

ANIMAL SAFETY

Margin of Safety: ProHeart 12 was subcutaneously administered to Beagle dogs (8 dogs per group) at 1X, 3X, and 5X the recommended dose of 0.5 mg/kg body weight on Days 1, 183, and 365. The control group (8 dogs) received saline injections. ProHeart 12 was well tolerated and did not result in any adverse systemic effects. ProHeart 12-related findings included edema and thickening of the injection site.

Ivermectin-Sensitive Collie Safety: In a laboratory study, 15 ivermectin-sensitive Collie dogs in three treatment groups were administered one dose of saline and one dose of ProHeart 12, 21 days apart. Each dog served as its own control and the order of administration of the saline and ProHeart 12 varied by treatment group. ProHeart 12 was dosed at 0.5 mg/kg body weight (1X, five dogs), 1.5 mg/kg body weight (3X, five dogs), or 2.5 mg/kg body weight (5X, five dogs). No clinical signs of moxidectin toxicity were observed during the 42-day study.

Heartworm-Positive Safety: In a laboratory study, 16 Beagle dogs implanted with adult heartworms (D. immitis) received either ProHeart 12 at 1.5 mg/kg body weight (3X, 8 dogs) or a saline injection

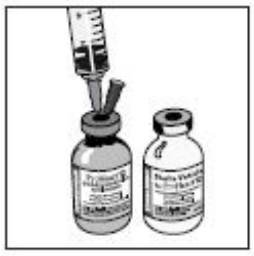
(control, 8 dogs). At 119 days post-infection (56 days post-moxidectin treatment), no adverse clinical signs and no gross pathological effects were noted in dogs with induced adult heartworm infections.

Reproductive Safety:
Females: A reproductive laboratory study in 40 female Beagle dogs assessed the safety of ProHeart 12 at a single 1.5 mg/kg body weight (3X) dose. The dogs were divided into four treatment groups of 8 dogs per group to cover the critical periods of the reproductive cycle (pre-mating, mating, mid-gestation, and lactation). The control group (8 dogs) were untreated. No adverse effects in terms of conception, pregnancy maintenance, and the development, growth, and health of the puppies were observed through puppy weaning at 6 weeks of age.
Males: A reproductive laboratory study assessed the safety of ProHeart 12 in eight male Beagle dogs at a single 1.5 mg/kg body weight (3X) dose. The control group (8 dogs) received a saline injection. No adverse reactions were noted in any of the dogs during the 91-day study. No clinically significant changes or abnormalities were noted in semen quality. Minor injection site thickening was noted by palpation in four dogs; all resolved within 13 weeks.

CONSTITUTION PROCEDURES

ProHeart 12 must be prepared at least 30 minutes prior to the first use.
Items needed to constitute ProHeart 12 10 mL (889 mg) product:
• Sterile vehicle vial- included
• Microspheres vial- included
• Vent needle (25G)- included
• Sterile 10 mL syringe for transfer- not included
• Transfer needle (18G or 20G) - not included

Constitution of the 10 mL vial product.
1. Shake the microsphere vial to break up any aggregates prior to constitution.
2. Using an 18G or 20G needle and sterile syringe withdraw 8 mL of the unique sterile vehicle from the vial.
There is more sterile vehicle supplied than the 8 mL required.
3. Insert the enclosed 25G vent needle into the microsphere vial.
4. Slowly transfer the 8 mL of sterile vehicle into the microsphere vial through the stopper using the transfer needle and syringe.
5. Once the sterile vehicle has been added, remove the vent and transfer needles from the microsphere vial.
Discard unused sterile vehicle and needles.
6. Shake the microsphere vial vigorously until a thoroughly mixed suspension is produced.
The product may appear as a hazy to milky suspension.
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 product may appear as a hazy to milky 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 8 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 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.

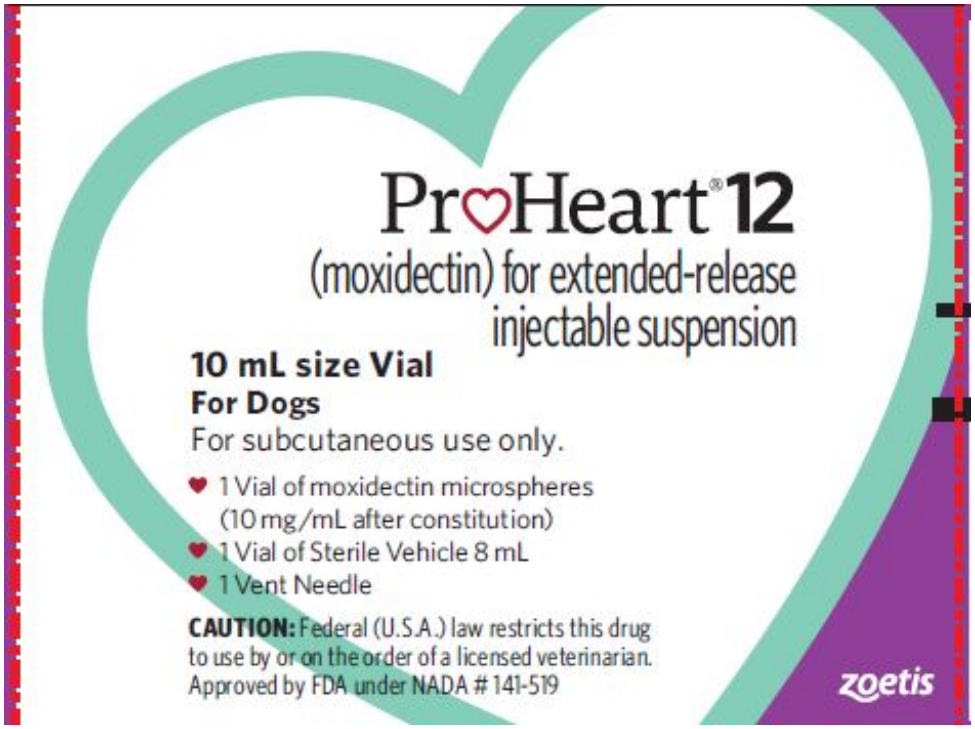
1-Pack	**5-Pack**	**10-Pack**
1 - 10% moxidectin sterile microspheres-889 mg/vial 1 - Sterile vehicle - 8 mL/vial	5 - 10% moxidectin sterile microspheres-889 mg/vial 5 - Sterile vehicle - 8 mL/vial	10 - 10% moxidectin sterile microspheres-889 mg/vial 10 - Sterile vehicle - 8 mL/vial

Approved by FDA under NADA # 141-519
Revised: April 2019

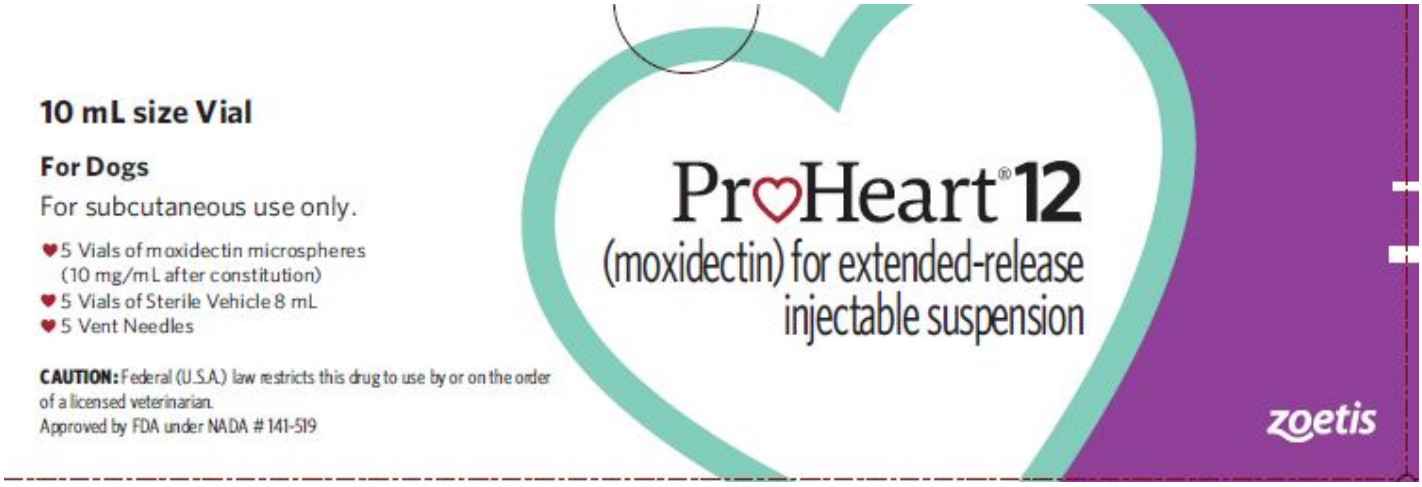
Zoetis
Distributed by: Zoetis Inc., Kalamazoo, MI 49007

40020054

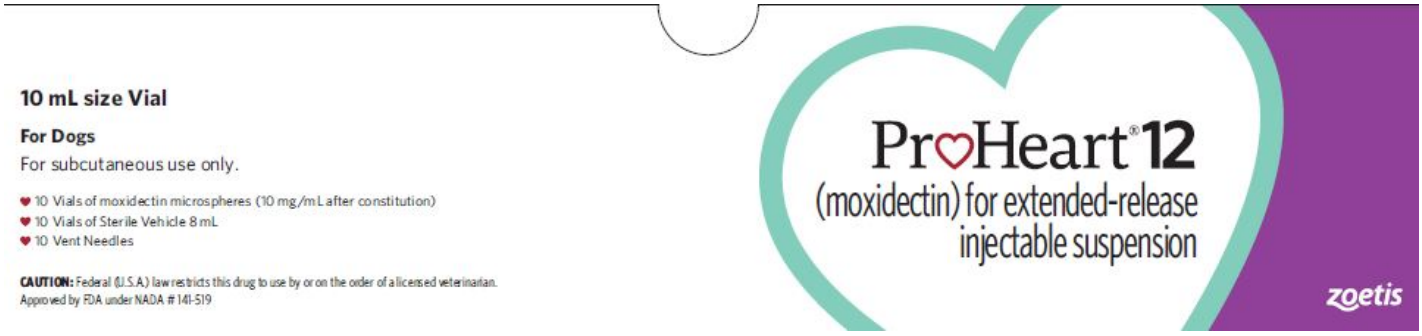
PRINCIPAL DISPLAY PANEL - 1 Vial Kit Carton



PRINCIPAL DISPLAY PANEL - 5 Vial Kit Carton



PRINCIPAL DISPLAY PANEL - 10 Vial Kit Carton



PROHEART 12

moxidectin kit

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:54771-0256

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54771-0256-1	1 in 1 CARTON		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	10 VIAL, MULTI-DOSE	10 mL
Part 2	1 VIAL	8 mL

Part 1 of 2

PROHEART 12

moxidectin injection, suspension, extended release

Product Information	
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MOXIDECTIN (UNII: NGU5H31YO9) (MOXIDECTIN - UNII:NGU5H31YO9)	MOXIDECTIN	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TRISTEARIN (UNII: P6OCJ2551R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

NADA	NADA141519	07/08/2019	

Part 2 of 2

STERILE VEHICLE

inert injection, suspension, extended release

Product Information

Route of Administration	SUBCUTANEOUS

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141519	07/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141519	07/08/2019	

PROHEART 12

moxidectin kit

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:54771-0254

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-0254-1	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	50 VIAL, MULTI-DOSE	50 mL in 5
Part 2	5 VIAL, MULTI-DOSE	40 mL in 5

Part 1 of 2

PROHEART 12

moxidectin injection, suspension, extended release

Product Information	
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MOXIDECTIN (UNII: NGU5H31YO9) (MOXIDECTIN - UNII:NGU5H31YO9)	MOXIDECTIN	10 mg in 1 mL

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Ingredient Name	**Strength**
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BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141519	07/08/2019	

Part 2 of 2

STERILE VEHICLE

inert injection, suspension, extended release

Product Information	
Route of Administration	SUBCUTANEOUS

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		8 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141519	07/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141519	07/08/2019	

PROHEART 12

moxidectin kit

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-0255

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-0255-1	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	10 VIAL, MULTI-DOSE	100 mL in 10
Part 2	10 VIAL, MULTI-DOSE	80 mL in 10

Part 1 of 2

PROHEART 12

moxidectin injection, suspension, extended release

Product Information

Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MOXIDECTIN (UNII: NGU5H31YO9) (MOXIDECTIN - UNII:NGU5H31YO9)	MOXIDECTIN	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
TRISTEARIN (UNII: P6OCJ2551R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 mL in 1 VIAL, MULTI-DOSE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141519	07/08/2019	

Part 2 of 2

STERILE VEHICLE

inert injection, suspension, extended release

Product Information	
Route of Administration	SUBCUTANEOUS

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 mL in 1 VIAL, MULTI-DOSE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141519	07/08/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141519	07/08/2019	

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