



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 6, 2016

W. Lance H. Hemsarth
Senior Director R&D
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Subject: Notification per PRN 98-10 – Minor Revisions and additional claim
Product Name: Hartz Reference #143
EPA Registration Number: 2596-178
Application Date: 1/12/2016
Decision Number: 513130

Dear Mr. Hemsarth:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed in a large, hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Hartz® Reference # 143

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

Hartz® Pro Force™ for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ for Dogs (&) (and Puppies)

Hartz® Pro Force™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
Hartz® First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

FieldForce Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
First Defense Pro™ Triple Action Topical Treatment for Dogs (&) (and Puppies)
First Defense Pro™ Triple Active Topical Treatment for Dogs (&) (and Puppies)

FieldForce Pro™ for Dogs (&) (and Puppies)
First Defense Pro™ for Dogs (&) (and Puppies)
FieldForce Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
First Defense Pro™ Triple Action Topical Solution for Dogs (&) (and Puppies)
First Defense Pro™ Triple Active Topical Solution for Dogs (&) (and Puppies)

NOTIFICATION

2596-178

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

02/06/2016

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	81.15%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS:

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 - 22 lbs.	0.023 fl. oz. (0.67 ml.)(Applicator)
23 - 44 lbs.	0.045 fl. oz. (1.34 ml.)(Applicator)
45 - 88 lbs.	0.091 fl. oz. (2.68 ml.)(Applicator)
89 – 132 lbs.	0.136 fl. oz. (4.02 ml.)(Applicator)

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 - 22 lbs.	0.069 fl. oz. (2.01 ml.), Contains 3(-) (tubes, each) 0.023 fl. oz. (0.67 ml.)(Applicators)
23 - 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 (-) (tubes, each) 0.045 fl. oz. (1.34 ml.)(Applicators)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3(-) (tubes, each) 0.091 fl. oz. (2.68 ml.)(Applicators)
89 – 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 (-) (tubes, each) 0.136 fl. oz. (4.02 ml.)(Applicators)

For use ONLY on Dogs and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 - 22 lbs.	0.138 fl. oz. (4.02 ml.), Contains 6 (-) (tubes, each) 0.023 fl. oz. (0.67 ml.)(Applicators)
23 - 44 lbs.	0.27 fl. oz. (8.04 ml.), Contains 6 (-) (tubes, each) 0.045 fl. oz. (1.34 ml.)(Applicators)
45 - 88 lbs.	0.546 fl. oz. (16.08 ml.), Contains 6 (-) (tubes, each) 0.091 fl. oz. (2.68 ml.)(Applicators)
89 – 132 lbs.	0.816 fl. oz. (24.12 ml.), Contains 6 (-) (tubes, each) 0.136 fl. oz. (4.02 ml.)(Applicators)



(1.5 x 1.5 cm icon)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panel. The icon will appear in a black lined yellow box.]

DO NOT USE ON CATS

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER
DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS
DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT
DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS
THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER



(Place in a 1.5 x 1.5 cm yellow box with black images only.)

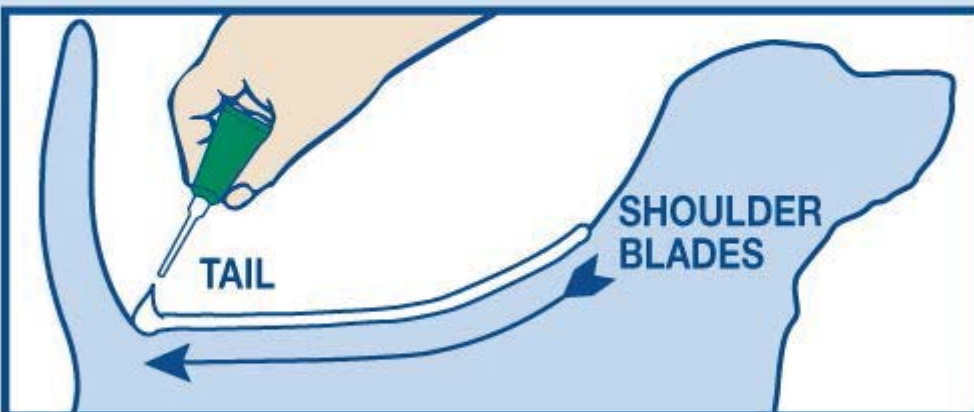
DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



3 Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

4 Repeat every month.

SIDE EFFECTS

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to three months. PRODUCT NAME also prevents development of all flea stages for up to three months. PRODUCT NAME kills ticks for at least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to three months, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

(With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.)

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal. Do not use or store near heat or open flame.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-178

EPA Est. No. 2596-OH-1

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

[Product name]

For use ONLY on DOGS AND PUPPIES 8 WEEKS OR OLDER weighing (*insert from weight range list below*) -

5 - 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 - 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains Fipronil (9.80%), (S)-Methoprene (8.80%), Pyriproxyfen (0.25%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

EPA Reg. No. 2596-178

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

[Adult Fleas]

Kills Fleas (for (28 days) (30 days) (1 month) (4 weeks))

Kills Fleas for (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas that may transmit tapeworm (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills newly emerged adult fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Starts killing fleas within 30 minutes* (mins)

*48 hours after initial application

[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (dog *or* puppy *or* dog and puppy) that live in your home

Kills flea eggs on your (dog *or* puppy *or* dog and puppy) to prevent the eggs from hatching in your home.

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

Kills fleas, (kills) flea eggs, (kills) flea larvae and (kills) ticks (including those that may transmit Lyme disease)

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, (Kills) Ticks, (Kills) Flea eggs, ((Kills) Flea larvae), (Kills) Chewing Lice

Kills Fleas, Ticks, Flea eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, Flea larvae, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, and Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks and chewing lice (for dogs and puppies 8 weeks or older)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs and puppies 8 weeks of age or older)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults in the home (for) (up to) (30 days) (1 month) (4 weeks)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation
Prevents and controls re-infestation(s)
Dual insect growth regulator (IGR) prevents re-infestation
Contains two ingredients to prevent flea infestations

Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
Waterproof
Effective after bathing
Effective after exposure to water
Easy spot on topical applicator
Patents Pending

Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Convenient to use
Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)
Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- **Fast Acting**
- **Long Lasting**
- **Waterproof**

Only for dogs and puppies 8 weeks of age or older
Specially formulated for dogs and puppies 8 weeks of age or older

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose, 4th dose, 5th dose, 6th dose
First month, second month, third month, fourth month, fifth month, sixth month
Value pack
1 month supply
3 month supply

6 month supply
1 (monthly) treatment
3 (monthly) treatment(s)
6 (monthly) treatment(s)
1 (monthly) dose
3 (monthly) doses
6 (monthly) doses
Apply (monthly) (every 30 days)
Convenient (easy to use) applicator
(3) Pro-cision Flo® Applicator(s) (included)
(Pro-cision Flo® Applicator)
Featuring Pro-cision Flo® Applicator (for easy application)
Direct to (your dog's) skin
(Easy) (simple) to use (handle) (apply)
Made in the U.S.A
Patent(s) Pending Formula

After application, the treated area may appear (wet) (or) (oily) for up to 24 hours
You may bathe your dog 48 hours after application

(Single Dose Pack) (Single Unit Pack) (Individual Unit) (Not For Sale)

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First (Dose)(Application)	_____
Second (Dose)(Application)	_____
Third (Dose)(Application)	_____
Fourth (Dose)(Application)	_____
Fifth (Dose)(Application)	_____
Sixth (Dose)(Application)	_____

To ensure continued protection of your pets, use these stickers as a reminder to apply and re-purchase (Brand name).

After treating your pet for the first time, peel off the sticker and place on your calendar that day. Place the remaining stickers on your calendar as a reminder to apply (Brand name) monthly.

Calendar Reminder Stickers

Don't forget to re-purchase

6 months use all 6 stickers

3 months (use all 3 stickers)

[Individual stickers] Apply (Brand name)

[Individual sticker] Re-purchase (Brand name)

Use these calendar stickers as a reminder for when to reapply

- (Apply) (First) (1st) Month (Brand Name)
- (Reapply) (Second) (2nd) Month (Brand Name)
- (Reapply) (Third) (3rd) Month (Brand Name) (Time to Re-purchase)
- (Reapply) (Fourth) (4th) Month (Brand Name)
- (Reapply) (Fifth) (5th) Month (Brand Name)
- (Reapply) (Sixth) (6th) Month (Brand Name) Time to Re-purchase

Questions?

Contact your veterinarian or call our technical experts at 1-800-275-1414, (twenty four) (24) hours per day, (seven) (7) days per week.

Consult veterinarian before use



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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

(Nylar[®] - Registered Trademark of McLaughlin Gormley King Company)

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