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|--|---|---|
| /IRONMENTAL PROTECTION AGENCY | EPA Registration No. | Date of Issuance: |
| Office of Pesticide Programs Registration Division (7504P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460-0001 | 2596-179 | APR # 4 2014 |
| AL PROTE | | |
| NOTICE OF PESTICIDE: ☑ Registration ☐ Reregistration (under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended) | Term of Issuance: Cond | itional , |
| | Name of Pesticide Produc | et: |
| | Hartz® Reference #144 | |
| The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-368 Note: Changes in labeling differing in substance from that accepted in coand accepted by the Registration Division prior to use of the label in always refer to the above EPA registration number. On the basis of information furnished by the registrant, the above nar Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recomprotect health and the environment, the Administrator, on his motion, mapesticide in accordance with the Act. The acceptance of any name in con Act is not to be construed as giving the registrant a right to exclusive use others. This action is taken under the authority of section 3(c)(7)(A) of the Fermi Power of the section 3(c)(7)(A) of the Section 3(c)(A) | med pesticide is hereby regis nmendation of this product b ay at any time suspend or car nection with the registration of the name or to its use if i | tered under the Federal y the Agency. In order to neel the registration of a of a product under this t has been covered by |
| amended. Registration under this section does not eliminate the need for require submission of data at any time to maintain the registration of you | continual reassessment of p | |
| 1. EPA has registered the product listed above provided that before you release the product for shipment: a. Revise the EPA Registration Number to read: "EPA Registration is time-limited and expires two years for shipment (April 4, 2016). You must provide the Agency writing within 30 days of the date of this Notice of Registration date based on the projected "release for shipment date" until a writing. | at the following changes a stration No 2596-179" (2) from the date this provided the projected "release on. The Agency will calc | roduct is first released for shipment date," in ulate the expiration |

Signature of Approving Official:

Refer to Page #3

APR 4 2014

Richard J. Gebken, Product Manager (10)

Registration Division, Insecticide Branch

- 5. You must submit the following data within the timeframe described below:
 Within twelve (12) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).
- 6. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on July 1, 2014. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division (attn: Kaitlin Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number

Product name (brand name)

Lot#

Where purchased: internet, store, Veterinarian

Active Ingredient(s)

Weight range for product

Date on which incident occurred, (mm/dd/yyyy)

State in which the incident occurred, (standard 2 letter abbreviation)

Registrant case #

Species: dog, cat, other (specify)

Breed: (as reported by pet owner)

Age: months or years Sex: M, F, or neutered

Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other

Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted

Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor Outcome: died, recovered, still treated, unknown

- 7. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - a. All minor dermal and ocular irritation reports.
 - b. Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code f
 - d. Summary table for cats and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - e. A summary table for s showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - f. A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label.
 - g. A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range.
 - h. Table showing number of incidents for each cat breed.
 - i. Table showing number of incidents in cat for each clinical sign.
 - j. Table showing number of incidents in cat for each organ system.
 - k. Report aggregate incidents, but do not combine moderate and minor incidents.

Page 3 of 3

- 8. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.
- 9. The Hartz Mountain Company must adequately address all of the mitigation actions identified in the Agency's Generic Pet Spot-On-Mitigation Plan available at the following internet site:

 http://www.epa.gov/pesticides/health/spot-on-meetings.html.

10. Enclosed is a copy of the data call-in (DCI) for fipronil.

You must submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records along with hard copies of the similarity clinic memo as well as the child-resistant packaging, companion animal safety data, efficacy, product chemistry reviews completed in support of the registration of this new product. If you have any questions concerning this letter, please contact Ms. Carlyn Petrella at (703) 347-0439 or via e-mail at <u>Petrella.Carlyn@epa.gov</u>.

Sincerely

Richard Gebken Product Manager 10 Insecticide Branch

Registration Division (7504P)

Enclosures:

Label Stamped "Accepted with Comments," dated April 4, 2014

Child-Resistant Packaging Review, dated March 10, 2014 Efficacy Review, dated March 18, 2014

Product Chemistry Review, dated March 7, 2014

Similarity Clinic Memo, dated December 11, 2013

Copy of DCI for Fipronil

002596-00179 D483629

Hartz[®] Reference #-144

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)

Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)

Hartz® First Defense ProTM Triple Action Topical Treatment for Cats (& Kittens)

Hartz® First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro ForceTM for Cats (& Kittens)

Hartz® FieldForce Pro™ for Cats (& Kittens)

Hartz® First Defense Pro™ for Cats (& Kittens)

Hartz® Pro Force™ Triple Action Topical Solution for Cats (& Kittens)

Hartz® FieldForce ProTM Triple Action Topical Solution for Cats (& Kittens)

Hartz® First Defense ProTM Triple Action Topical Solution for Cats (& Kittens)

Hartz® First Defense ProTM Triple Active Topical Solution for Cats (& Kittens)

FieldForce ProTM Triple Action Topical Treatment for Cats (& Kittens)

First Defense ProTM Triple Action Topical Treatment for Cats (& Kittens)

First Defense ProTM Triple Active Topical Treatment for Cats (& Kittens)

FieldForce ProTM for Cats (& Kittens)

First Defense ProTM for Cats (& Kittens)

FieldForce ProTM Triple Action Topical Solution for Cats (& Kittens)

First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)

First Defense ProTM Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

| Fipronil | 9.80% |
|-------------------|--------|
| (S)-Methoprene | 11.80% |
| Pyriproxyfen | |
| OTHER INGREDIENTS | |
| TOTAL | 00.00% |

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: 0.051 FL. OZ. (1.5 ML), Contains 3 tubes, each 0.017fl. oz. (0.5ml)

For use ONLY on cats & kittens 8 weeks and older, weighing 3 lbs. or more.

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 or using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. 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 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.

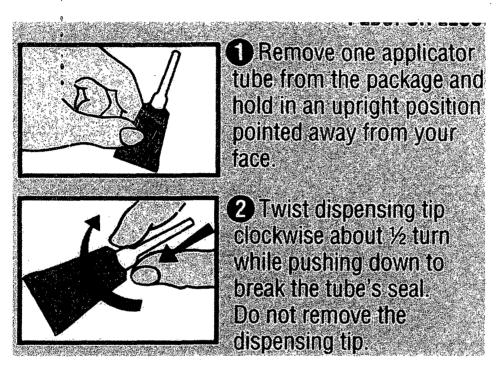
IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

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. TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS.

DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deed ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:



- 3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
- 4. Repeat once a month.

SIDE EFFECTS

Monitor your cat 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.

PRODUCT NAME 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, chewing like and mosquitoes.

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 six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, 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-EPA Est. No. 2596-OH-1

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INDIVIDUAL TUBE TEXT

(Product Name)

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5ml)

Contains Fipronil 9.8%, (S)-Methoprene 11.8%, Pyriproxyfen (Nylar®) 0.25%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

Product Name 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, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

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

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American

Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

Kills (Adult) Fleas

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 and 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) Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8-weeks-or-older-weighing-3-lbs-or-more

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

[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 (cat or kitten or cat and kitten) that live in your home

Kills flea eggs on your (cat or kitten or cat and kitten) 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 (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

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

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

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

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

Kills Fleas, Ticks, Flea Eggs through contact (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 through 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)

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

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

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, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

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 cats) Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

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 (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

April 3, 2014

Hartz [®] Reference #144 EPA Reg. No.: 2596-MASTER LABEL- -

(With) patented applicator

(With) patent pending applicator

Waterproof

Effective after bathing

Effective after exposure to water

Patents Pending

Easy spot on topical applicator

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 (Pyriproxyfem) (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 cats and kittens 8 weeks of age or older weighing 3 lbs or more Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose

First month, second month, third month

Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

With Pro-cision Flo®Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

12/12

Hartz [®] Reference #144 EPA Reg. No.: 2596-MASTER LABEL- -

April 3, 2014

| After application, the treated area may appear wet (or) (oily) for You may bathe your cat 48 hours after application To help remind you when you last applied treatment, simply wri | ; |
|---|----------------------------------|
| applied: | te in the date with each dose is |
| * * | • |
| First Dose | 9 |
| Second Dose | ì |
| Third Dose | |
| | , · |
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