

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

March 26, 2024

Lisa Adamson Regulatory Manager Control Solutions, Inc. 5903 Genoa Red Bluff Rd Pasadena, TX 775007

Subject: Notification per PRN 98-10 – Add optional graphics and text Product Name: Prefurred Plus IGR for Cats EPA Registration Number: 53883-352 Application Date: 3/6/2024 Case Number: 557476

Dear Lisa Adamson:

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 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 (FIFRA) 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) lists 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, please contact Rebecca Lasko at 202-565-2469 or at lasko.rebecca@epa.gov.

Sincerely,

Rebeccadarks for

Scott Campbell, Acting Product Manager 3 Invertebrate & Vertebrate Branch 1 Registration Division (7505T) Office of Pesticide Programs

Information in [] is optional Text in () is meant to be included on the label Information in {} is a note to the reviewer

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Prefurred Plus IGR for Cats

Prefurred Plus IGR for Cats {The CRP packaging to be used for this product is described as a CRP blister applicator and is supplied as a 3 count in strips.

Information in [] is optional Text in () is meant to be included on the label

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{CARTON/POUCH LABEL - DRAFT MASTER LABEL COPY}

{Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, back booklet, side, or on insert. The CRP required text will not change.}

{start of front panel}

Prefurred Plus IGR for Cats

{The word Cat is to be at least 75% the height of the largest letter in the primary brand name.} {ABNs:}

[Martin's FLEETM Plus IGR for Cats]

{The below picture of a cat in the weight range for the product as packaged will appear on the front panel of the label.}



NOTIFICATION

53883-352

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:

03/26/2024

For use ONLY on cats [&] [and] kittens over 1.5 lbs and over 8 weeks of age {OR} Only for cats [&] [and] kittens over 8 weeks of age and over 1.5 lbs {**One of the above statements will appear on front panel in a text box**}

[Prevents infestation of listed pests for [4 weeks][1 month] [30 days]] {only one of these will be used consistently throughout the label}

[Lift [here] for more information]

ACTIVE INGREDIENTS:

Fipronil	9.80%
(S)-methoprene	
OTHER INGREDIENT:	
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

See[Back][or][Side][Label[s]][Panel[s]] [Insert] for First Aid and Additional Precautionary Statements

See [back booklet] [or] [insert] and back panel for complete Directions for Use.

 $\label{eq:linear_state} \begin{array}{l} \mbox{Net Contents: [0.017]{for one count} [0.051]{for three count} [0.102]{for six count} fl oz \\ \mbox{[One][1] - 0.017 fl oz (0.53 mL) applicator] [3 - 0.017 fl oz (0.503 mL) applicator(s)] [6 - 0.017 fl oz (0.503 mL) applicator(s)] \\ \mbox{fl oz (0.503 mL) applicator(s)]} \end{array}$

[[1][3] [6] [One] [Three] [Six] Applications] [[1][3] [6] [One] [Three] [Six] Month Supply] November 22, 2021 53883-352

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{END - FRONT PANEL}

{START -BACK PANEL OR BACK BOOKLET}

[[Brand name][This product] contains Fipronil and S-Methoprene [insect growth regulator] [IGR] to kill fleas (all stages) and ticks [(including those that may transmit Lyme disease)]. [The active ingredients in [Brand name][this product] feature a sustained release formula developed for control of fleas, ticks, [mosquitoes] and chewing lice for [1 month][4 weeks] [30 days] on cats only.]

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE AND OVER 1.5 LBS.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, 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 on cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, or aged cats. Can be used on breeding, pregnant, or lactating [cats] [female cats] [queens]. Consult a veterinarian before using on cats with known organ dysfunction. This product is not a substitute for prescribed Heartworm preventative.

FIRST AID {will be located on back panel or 1 st page of back booklet}				
If swallowed:	Call a poison control center or a 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.Call a poision control center or doctor for treatment advice.			
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.			
HOT LINE NUMBER				
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact SafetyCall at 1-866-897-8050 for emergency medical treatment information.				

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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 CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

<u>Restrictions {will be on insert}</u> Do not use on rabbits or animals other than cats. Do not allow your cat to ingest this product. Do not use on cats or kittens under 8 weeks of age. Do not apply to cats weighing less than 1.5 lbs.

Use entire contents of applicator on each cat.

Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied. Do not apply more than one applicator per treatment for one cat regardless of cat's weight. Do not bathe or allow water immersion (swimming) for 24 hours after application. The cat needs to be dry at the time application and remain dry for 24 hours after application. Do not apply more often than once every [4 weeks] [month] [30 days].

Side Effects: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. Gastrointestinal signs such as vomiting, or diarrhea have also been reported. If these or other side effects occur consult your veterinarian or call 1-800-781-4738. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. *Note to reviewer: {A box labeled "Side Effects" will be located in the lower right hand corner of the back panel.*]

FREQUENCY OF APPLICATION

Use [Brand name][this product] monthly [every 4 weeks] for control of flea, tick [and] chewing lice [and mosquito] infestations. Apply [monthly] [every 4 weeks] [every 30 days] to prevent flea reinfestation on your cat. Apply [monthly] [every 4 weeks] [every 30 days] to control ticks[,] [mosquitoes] and chewing lice. [Brand name][This product] remains effective, even after bathing, water immersion, or exposure to sunlight 24 hours after application. Allow treated area to dry thoroughly before touching. Do not reapply for [1 month] [4 weeks] [every 30 days]. [[Brand name][This product] can be used on breeding, pregnant and lactating (queens) (female cats).]

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{located on back panel}

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove applicator from the pack until ready to use. Store in a cool (below 77°F[/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: 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.

[[WARRANTY] {Will appear on back or side panel or inside back booklet IF insert is not used; otherwise it will be on insert only}

LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. To the extent consistent with applicable law, by using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES**, and **LIMITATIONS OF LIABILITY**.

CONDITIONS: The directions for use of this product must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product, or the manner of use or application, all of which are beyond the control of Control Solutions, Inc. All such risks shall be assumed by the user or buyer, to the extent consistent with applicable law.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Control Solutions, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Control Solutions, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Control Solutions, Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Control Solutions, Inc. election, the replacement of product.]

[If you have questions or comments about this product, please write: CSI Consumer Response, 5903 Genoa-Red Bluff Road, Pasadena, TX 77507]

[In Case of Emergency, call: XXX-XXX-XXXX] [For more information]

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[Non-Emergency, call XXX-XXX-XXX]

{batch code will be printed somewhere on box}

Distributed by: Control Solutions, Inc. 5903 Genoa-Red Bluff Road Pasadena, TX 77507



EPA Reg. No. 53883-352 EPA Est. No. XXXXX-XXXX

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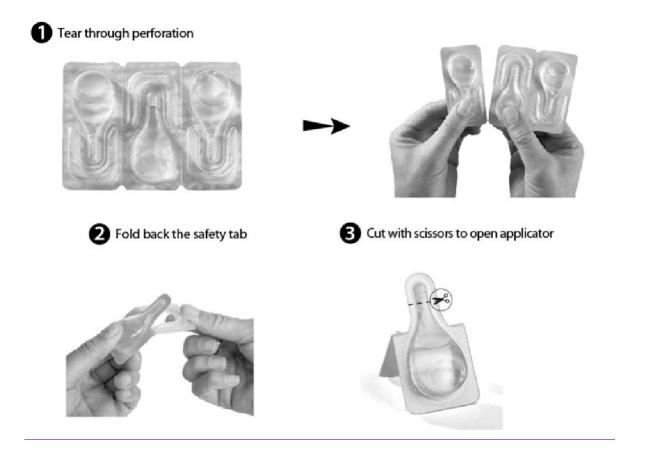
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{ The CRP blister applicator 3-Count SAUE opening instructions will be used and the term "applicator" will be used consistently throughout the label.}

{CRP blister applicator 3-count package}

How to Open:



Information in [] is optional Text in () is meant to be included on the label Information in {} is a note to the reviewer

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{Begin "How to Apply" for applicator (3-Countt) The term "applicator" will be use with this CRP package and will be used consistently throughout the label.}

How to Apply: {will appear for 3 applicator packages and will appear on back panel or in back booklet if pouch configuration is used }

- 1. Invert applicator over cat and use open end to part cat's hair.
- 2. Apply contents of one applicator of {**Brand Name**} [as a stripe, starting high [on] [to] the back of the cat's neck to in front of the shoulder blades] [as a spot between the shoulder blades]. Squeeze applicator firmly to apply all of the solution to the cat's skin.]

{END – BACK PANEL OR BACK BOOKET}

Information in [] is optional Text in () is meant to be included on the label Information in {} is a note to the reviewer

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{START OF INSERT – INSERT WILL ONLY BE USED ON CARTON CONFIGURATION. IF BACK BOOKLET IS USED, THE INSERT WILL NOT BE USED}



[[Brand name][This product] contains Fipronil and S-Methoprene [insect growth regulator] [IGR] to kill fleas (all stages) and ticks [(including those that may transmit Lyme disease)]. [The active ingredients in [Brand name][this product] feature a sustained release formula developed for control of fleas, ticks, [mosquitoes] and chewing lice for [1 month][4 weeks] [30 days] on cats only.] {only one of these options will be used throughout the label.}

WARRANTY

LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. To the extent consistent with applicable law, by using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES**, and **LIMITATIONS OF LIABILITY**.

CONDITIONS: The directions for use of this product must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product, or the manner of use or application, all of which are be

eliminate all risk associated with the use of this product, or the manner of use or application, all of which are beyond the control of Control Solutions, Inc. All such risks shall be assumed by the user or buyer, to the extent consistent with applicable law.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Control Solutions, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Control Solutions, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Control Solutions, Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Control Solutions, Inc. election, the replacement of product.

DIRECTIONS FOR USE

Restrictions

Do not use on rabbits or animals other than cats. Do not allow your cat to ingest this product. Do not use on cats or kittens under 8 weeks of age. Do not apply to cats weighing less than 1.5 lbs.

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Use entire contents of applicator on each cat.

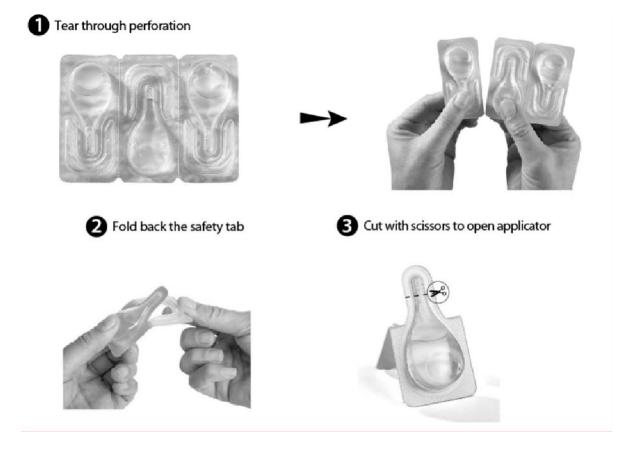
Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied. Do not apply more than one applicator per treatment for one cat regardless of cat's weight. Do not bathe or allow water immersion (swimming) for 24 hours after application. The cat needs to be dry at the time application and remain dry for 24 hours after application.

Do not apply more often than once every [4 weeks] [month] [30 days].

{The CRP blister applicator 3-Count SAUE opening instructions will be used and the term "applicator" will be used consistently throughout the label.}

{CRP blister applicator 3-count package}

How to Open:



Information in [] is optional Text in () is meant to be included on the label

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Information in { } is a note to the reviewer

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How to Open

- 1. Remove product tubes from the package
- 2. [Separate one tube from the others.] {this will only be optional on the one count package} Hold the tube with notched end pointing up and away from the face and body.
- 3. Use scissors to cut off the narrow end at the notches along the line.



How to Apply

- 1. Invert tube over cat and use open end to part cat's hair.
- 2. Squeeze tube firmly to apply all of the solution to the cat's skin as a spot on the cat's skin as a spot on the cat's back between the shoulder blades.

{How to apply information will be found on back panel}



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{END OF INSERT}

{Optional Claims}

{The claims will be located on the front panel//front of box, back of box inside back booklet or on insert}

[Look at the Label (Look at the Label icon) [Easy] 7 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow all directions for use.
- [2] Weigh your cat
- [3] Do NOT use this product on dogs
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate treated cats from each other and other pets until product has dried to avoid chance of ingestion
- [6] Do NOT split applicators between cats[and use the ENTIRE applicator contents]and do not use more than one applicator [a month] [every 4 weeks] [every 30 days]
- [7] Do NOT apply more than one tube per treatment for one cat regardless of the cat's weight.

[Brand Name]

[Monthly reminder card]

[3] Month [Treatment] [Application] Tracker]

[For year round protection apply [Brand name][This product] monthly.]

[Cat's Name {Empty blank for owner to fill in name}]

[First][1st][Second][2nd][Third][3rd]

[Dose] [Treatment] [Application] {Empty blank for owner to fill in date } (Date: MM/DD/YY)] [calendar stickers with [Brand name][This product] [Place stickers on your calendar as a reminder to reapply [Brand name][This product] in [30 days][4 weeks][a month].]

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{Optional graphics below may or may not appear anywhere on finished label}

Toto	Adult Flea	
TAN	Fleas	
-26	Flea eggs	S
っ	Flea Larvae	3
	Flea Pupae	
	Ticks	
	Brown Dog Tick	8
	Deer Tick	
*	American Dog Tick	
*	Chewing Lice	
*	Lone Star Tick	
₹¥	Mosquitoes	





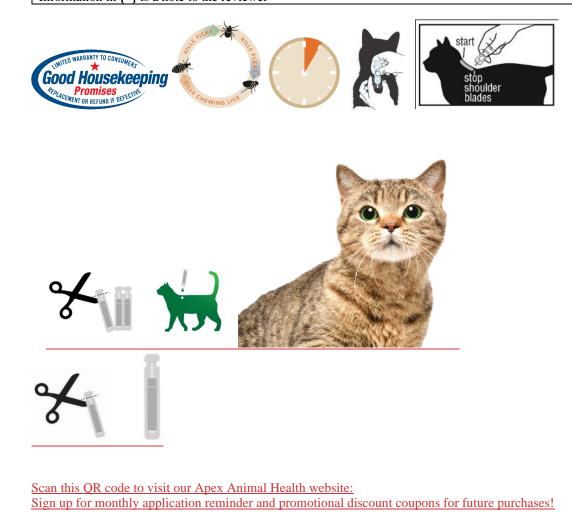




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[Flea life cycle diagram] [Flea Life Cycle]

{START – BLISTER APPLICATOR LABEL} {the below text will be on each separate blister applicator along with the embossed lot number} {each blister applicator has a clear plastic front and white foil backing with black printing}

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{Printed on back of blister applicator}	
{Brand Name}	KEEP OUT OF REACH OF CHILDREN
For Cats over 1.5 lbs and over 8wks [of age]	CAUTION: Read entire label before use. Use
Fipronil 9.8%, (S)-methoprene 11.8%	scissors to open.
0.017 fl oz (0.503 mL) {label code}	EPA REG. No. 53883-352 {label code}
	Lot Number:

{END – APPLICATOR LABEL}

{**Mosquitoes**} [Kills mosquitoes]

{Chewing Lice} [Kills chewing lice]

{Adult Fleas}
[Kills adult fleas]
[Kills Fleas [[one month] [4 weeks] [30 days] on cats]!]
[Kills fleas which may cause flea allergy dermatitis] [or flea bite anemia]

{Ticks}

[Kills ticks including those that may transmit Lyme disease]
[Kills Ticks for [4 weeks] [1 month] [30 days]!]
[Kills Deer Ticks (that may carry Lyme disease) for [4 weeks] [1 month] [30 days]]
[Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks][,][and deer ticks] [for [4 weeks] [1 month] [30 days]]]
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

{Multiple Infestations}

[Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older and over 1.5 lbs.]
[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]
[Kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [and] flea larvae [and prevents the development of flea pupae]]
[Breaks the Flea Life Cycle]
[Monthly protection from flea, tick, [mosquito,] chewing lice, and flea eggs for cats]
[Monthly protection from flea, tick, [mosquito] and chewing lice for cats]
[Kills fleas, ticks, [mosquitoes,] flea eggs, and chewing lice]
[[Seven] [7] [Six] [6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, flea larvae and prevents the development of flea pupae]
[[Six] [6] [Five] [5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs & flea larvae]

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[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]
[[Four (4) Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]
[Use [Brand name][this product] monthly to break the flea life cycle.]
[[Four (4) Week] [1 month] [30 day] [Flea, Tick and Chewing Lice Control]
[Use [Brand name][This product] monthly to control ticks and chewing lice]
[Monthly protection from flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]
[[4 week] [1 month] [30 day] Flea and Tick Treatment!]
[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]
[Kills Fleas and Ticks for [4 weeks] [1 month] [30 days]!]
[Kills Fleas, Ticks, Flea Eggs & Flea Larvae for [4 Weeks] [1 month] [30 days]]
[Brand name][This product provides convenient and effective flea, tick, [and] chewing lice [and] [mosquito] control for cats and kittens 8 weeks of age and older and over 1.5 lbs.]

{Flea Eggs and Larvae}

[Prevents reinfestation on your cat] [Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae] [Kills all stages of the flea (adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)] [For cats at high risk for flea reinfestation, apply once a month]

[With (S)-methoprene [Insect Growth Regulator] [IGR] which Breaks the Flea Life Cycle]
[With (S)-methoprene to Break Flea Life Cycle]
[With [Insect Growth Regulator] [IGR] to Break Flea Life Cycle]
[Dual Action [!]: Fipronil with (S)-methoprene [insect growth regulator] [IGR] Breaks the Flea Life Cycle]

[Prevents Flea Eggs From Developing Into Biting Adults]

{All Others}

[For Cats and Kittens over 1.5 lbs. and 8 weeks of age or older] [Can be used on kittens over 1.5 lbs. and 8 weeks of age and older] [Formulated for Cats and Kittens over 1.5 lbs. and Over 8 Weeks Old]

[Easy to Use [Application]] [Best if used year round!] [Apply [monthly][every 4 weeks][every 30 days]] [Once [a month][every 4 weeks][every 30 days] treatment] [Apply once every [4 weeks] [month] [30 days]!] [4 Week Dose!] [1 Month Dose!] [30 Day Dose!] [Three Applications] and/or [3 Month Supply] [Waterproof after 24 hours] [Effective even after bathing] [Effective after bathing and exposure to water and sunlight after 24 hours] [Can be used on breeding, pregnant and lactating [queens], [female] [cats]] [[Free] Calendar Stickers Inside!] [Monthly application reminder inside] [[Free with purchase] [Free inside] Monthly Application Reminder [inside]] {Neither of the "Free" statements will stand alone. It will be placed with the Monthly application reminder} [Resealable Pouch]

{Note to Reviewer: Comparison claim will not be presented with heavily bolded or highlighted type or use

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coloring to cause the claim to excessively stand out over the rest of the labeling text. The format of the claim will not be in such a way that it causes greater attention than other required precautionary labeling on the label.}

{the three below claims will be printed together on packaging}

Contains fipronil and (S) methoprene, the active ingredients used in FRONTLINE[®] Plus for Cats]. FRONTLINE[®] is a registered trademark of Merial.

Preferred Plus IGR for Cats is not manufactured, or distributed by Merial, seller of FRONTLINE[®] Plus for Cats.