



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Registration Division (7505P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

92413-1

Date of Issuance:

8/28/17

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 08/28/2019

Name of Pesticide Product:

Tevra Fipronil + Methoprene Spot-On for Cats

Name and Address of Registrant (include ZIP Code):

Dr. Olaf Hansen
 Tevra Brands, LLC.
 9100 F Street, Suite 200
 Omaha, NE 68127

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(C). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Elizabeth Fertich, Acting Product Manager 03
 Invertebrate & Vertebrate Branch 1
 Registration Division (7505P)

Date:

8/28/17

EPA Form 8570-6

2. This registration is time-limited and expires 08/28/2019.

3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. 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 with separate column for each sign, using standard terminology
 - 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

4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs 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.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs 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.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Fipronil GDCI-129121-1305
 - b. Fipronil GDCI-129121-1512

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

6. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
7. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 92413-1.”
8. Submit one copy of the final printed label for the record before you release the product for shipment.

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.

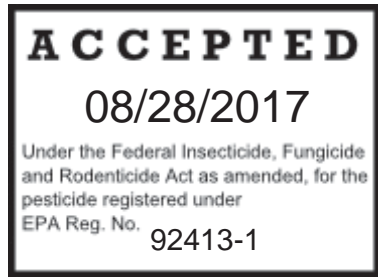
If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 05/16/2017
- Alternate CSF 1 dated 05/16/2017

If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Enclosure



Tevra Fipronil + Methoprene Spot-On for Cats

{Text in braces { } include notes to reviewer and positional designations}
{Optional text appears in brackets []– the final product label may include some or all of the optional text on front, back, side panels. The CRP required text and format will not change.}

{FRONT PANEL OF CARTON}

Tevra Fipronil + Methoprene Spot-On for Cats

{Note to reviewer: The word "Cats" will be 75% the height of the largest letter in the brand name}

{Note to reviewer: Please see ABNs at the end of this document}

{Note to reviewer: There will be a large, clear picture of a cat in the weight range of the product as packaged on the front panel}

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

[Apply only to cats and kittens over 8 weeks old and weighing over 1.5 lbs.]
[Apply only to cats and kittens 8 weeks or older and weighing over 1.5 lbs.]

ACTIVE INGREDIENTS:

| | |
|---------------------------------|---------------|
| Fipronil | 9.80% |
| (S)-methoprene | 11.80% |
| OTHER INGREDIENTS: | <u>78.40%</u> |
| TOTAL | 100.00% |

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

{Note to reviewer: Font size of the KOOROC statement and Signal word will be in compliance with Label Review Manual Ch. 3.}

See [Back][or][Side][Label[s]][Panel[s]] for First Aid, Precautionary Statements and Directions for Use

Net Contents: Z fl oz ; Y – 0.017 fl oz (0.50 mL) applicators

{OR}

Net Contents: Z fl oz; Y – X fl oz applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][7][Seven][8][Eight][12][Twelve]

{Note to reviewer: X is the liquid amount of one applicator; Y is the number of applicators that are in the carton; Z is the sum of the liquid amounts}

{END - FRONT PANEL}

{BACK PANEL/SIDE PANEL OF CARTON}

[[Brand name]][This product] contains Fipronil and S-Methoprene [insect growth regulator] [IGR] to effectively kill fleas . [The active ingredients in [Brand name]][this product] features a formula for long lasting control of fleas, and chewing lice for [1 month][4 weeks] 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 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.

FIRST AID

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 the 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.

If on Skin

- 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.

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 1-800-775-9416 for emergency medical treatment information.

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.

RESTRICTIONS

Do not use on rabbits or animals other than cats. Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 1.5 lbs. Do not apply more than one applicator per treatment for one cat regardless of the cat's weight. Use entire contents of applicator on each cat. [Do not split one applicator between two cats.] Cat must be dry at the time of application and remain dry for 24 hours after application. Do not allow your cat to ingest this product. Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied to allow product to dry thoroughly.

{Note to reviewer: A box labeled "Side Effects" is located in the lower right hand corner of the back panel}

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. If these or other side effects occur consult your veterinarian or call 1-800-775-9416. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application.

{How to Apply - May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.}

[[Clip. Part. Squeeze.]]

Easier-than-ever applicator lets you **clip** the tip, **part** the fur and **apply** directly to the skin – putting flea protection where it needs to be.]

[Application Instructions] [Directions for Use]

How to Open:

{If package contains strips of 3}

1 Tear through perforation



2 Fold back the safety tab



3 Cut with scissors to open applicator



{If package contains individual applicators}

1 Fold back the safety tab



2 Cut with scissors to open applicator

How to Apply:

1. Invert tube over cat and use open end to part cat's hair.
2. Apply contents of one applicator of [Brand name][this product] as a spot between the shoulder blades. Squeeze applicator firmly to apply all of the solution to the cat's skin.

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [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 the treated cat from other pets after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split applicators between cats [and use the ENTIRE tube contents]

FREQUENCY OF APPLICATION

Use [Brand name][this product] monthly for control of flea, chewing lice infestations. [Studies show that] [Brand name][this product] kills adult fleas for up to four weeks. Apply monthly if your cat is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control chewing lice. [Brand name] Allow treated area to dry thoroughly for 24 hours. Do not reapply for [30 days] [4 weeks]. [[Brand name][This product] can be used on breeding, pregnant and lactating (queens) (female cats).]

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

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. If empty: Do not reuse or refill this container. Place in trash or 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** Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer.]

Tevra Brands is committed to providing high quality products. To the extent consistent with applicable law, Tevra Brands makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Tevra Brands, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: Tevra Brands Pet Owner Response, 9100 F Street, Suite 200, Omaha Nebraska 68127]

In Case of Emergency, call: 1-800-775-9416

Non-Emergency, call: 1-844-276-3290

[Distributed by:][Manufactured by:]

Tevra Brands, LLC.

9100 F Street, Suite 200

Omaha Nebraska 68127

[Manufactured for the USA]

[BAR CODE AREA]

EPA Reg. No. 92413 - xxx

EPA Est. No. XXXXX-XX-XXX

{END - BACK / SIDE PANEL OF CARTON}

{APPLICATOR LABEL}

Brand Name

For Cats over 1.5 lbs and \geq 8wks

Fipronil 9.8%, (S)-methoprene 11.8%

0.017 fl oz

Lot #

For external use on cats only.

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read entire label before using. Use scissors to open.

EPA REG. No. 92413 - xxx

{END – APPLICATOR LABEL}

{OPTIONAL CLAIMS}

[Chewing Lice]

[Kills chewing lice]

[Rapid elimination of chewing lice infestation]

[Fast Action against chewing lice infestations]

[Adult Fleas]

[Kills adult fleas [for up to 4 weeks]]

[Kills Fleas [Up to [4] weeks]!]

[Kills fleas which may be a source of flea allergy dermatitis] [or flea bite anemia]

[Multiple Infestations]

[Flea Control for Cats [&] [and] Kittens 8 weeks old and older weighing over 1.5 lbs]

[Kills fleas [& flea eggs] [&] [chewing lice]]

[Breaks the Flea Life Cycle]

[Monthly protection from fleas, chewing lice, and flea eggs.]

[Monthly protection from fleas and chewing lice.]

[Kills fleas and chewing lice]

Tevra Fipronil + Methoprene Spot-On for Cats – 92413-R

[Control] [kills fleas[,] [&] chewing lice [&] [flea eggs]]
[[4 week] [1 month] [30 day] Flea [Application] [Treatment]!]
[[Four (4) Week] [1 month] [Flea, and Chewing Lice Control]
[Use [Brand name][this product] monthly to break the flea life cycle.]
[[Four (4) Week] [1 month] [30 day] [Flea and Chewing Lice Control]
[Use [Brand name][This product] monthly to control chewing lice]
[Monthly protection from fleas, flea eggs, and chewing lice.]
[[4 week] [1 month] [30 day] Flea Treatment!]
[Once A Month Flea, [and] [Chewing Lice][Application] [Treatment]]
[Kills Fleas for up to [4 weeks] [1 month] [30 days]!]
[Kills Fleas & Flea Eggs for up to [4 Weeks] [1 month] [30 days]]
[Brand name][This product provides convenient and effective flea [and] chewing lice control for cats
and kittens over 8 weeks of age and weighing over 1.5 lbs.]

[Flea Eggs]

[Kills adult fleas [for up to 30 days]]
[If cat is 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] Effectively Breaks the
Flea Life Cycle]
[Effectively Breaks the Flea Life Cycle[!]]
[Prevents Flea Eggs From Developing Into Biting Adults for 30 days]

[All Others]

[For Cats and Kittens 8 weeks of age or older and weighing over 1.5 lbs.]
[Can be used on kittens 8 weeks of age or older and weighing over 1.5 lbs.]
[Formulated for Cats and Kittens Over 8 Weeks Old and weighing over 1.5 lbs.]
[Long Lasting]
[Easy to Use [Application]]
[Best if used year round!]
[Apply monthly]
[Once a month treatment]
[Apply once every [4 weeks] [month] [30 days]!]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[3 Way Protection from fleas, chewing lice, and flea eggs for up to [1 Month][4 weeks]]
[3 Way Protection icons fleas, chewing lice and flea eggs]
[One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six
Applications][Twelve Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4
Month Supply][5 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week
Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][52
Week Supply]
[Fragrance Free]
[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 [Magnet] [clip] [inside]]
[Fipronil (9.8%) + (S)-methoprene (11.8%)]

[Contains the same active ingredients used in FRONTLINE® Plus for Cats*]
[Contains the same active ingredients as FRONTLINE® Plus for Cats*]
[Contains the same active ingredients, fipronil and (S)-Methoprene, as FRONTLINE® Plus for Cats.*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, the same active ingredients used in FRONTLINE® Plus for Cats*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, the same active ingredients used in FRONTLINE® Plus for Cats*]

{Note to reviewer: Whenever one of the claims above designated with "*" is used, the claims below will be located on the same panel so they can be read together.}

[*[Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers of FRONTLINE® Plus for Cats]
[*[Brand Name][Frontline®] is a registered trademark of [Merial®] [Company name].]

[[1][2][3][4][5][6][12][24] Applications]
[Stops and prevents infestation of listed pests for [4 weeks][1 month]]
[Direct to skin] [applicator]
[Easy to Use] [applicator]
[Clean cut [open] [applicator]]
[No-mess [open] [applicator]]
[Clip-tip design [applicator] [!]]
[Satisfaction Guaranteed - If you are not satisfied, we will make it right with a replacement or refund.]
[Save Now!]
[Value Size]
[Club Size]
[Bonus Size]
[Club Pack]
[Great Value]
[Better Value]
[Bonus Pack]

{Note to Reviewer: Buying a larger pack reduces the price, therefore the cost effective without the addition of extra applicators; Combinations of "x" and "y" will correspond to the Net Contents; All applicators will be included inside the carton.}

[(x) + (x) bonus pack!]
[Buy more and save!]
[Buy X Get Y Free]
[Buy 3 get 1 free]
[(x)% (More) (Free)!]
[33% more free]
[(x) Dose(s) Free!]
[(x) Day(s) (Free)!]

[(x) Month(s) Free!]
[(x) Day(s) of treatment- Free!]
[(x) Applicator(s) Free!]
[(x) Application(s) Free!]

[Monthly reminder card]

[Brand Name]
[Monthly reminder card]
[3 Month [Treatment] [Application] Tracker][Carecard]
[For year round protection apply [Brand name][This product] monthly.]
[Cat's Name]
[Cat's Weight]
[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th]
[Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]
[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)
[Application date][Date of Application]

[Calendar Stickers]

[calendar stickers with [Brand name][This product]
[Place stickers on your calendar as a reminder to reapply [Brand name][This product] in 30 days.]
[Place sticker on your calendar or [refrigerator] to remind yourself to apply [Brand name][this product] to your cat]

[Monthly Application Reminder Magnet]

[Monthly Application Reminder Magnet (image of reminder magnet)]
[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand name][This product] . Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

{Optional graphics below may or may not appear anywhere on finished label}
[Adult Flea, Fleas, Flea eggs, Chewing Lice, Flea life cycle diagram, Flea Life Cycle]



[ABNs:]

Tevrapet for Cats
FirstAct Plus for Cats
Tevrapet FirstAct™ Plus for Cats
Vetality Firstect™Plus for Cats
Firstect™ Plus for Cats
FirstPet Plus for Cats
Tevra Fipronil + Methoprene Spot-On for Cats – 92413-R

Vetality™ Plus for Cats

Frontrunner™ Plus for Cats