



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

EPA Reg. Number:

91300-6

Date of Issuance:

10/4/16

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 10/04/2018

Name of Pesticide Product:

Promika ZoGuard Plus for Cats

Name and Address of Registrant (include ZIP Code):

Ann. M. Tillman, Ph.D.
 Promika, LLC
 c/o Pyxis Regulatory Consulting, Inc.
 4110 136th Street. CT NW
 Gig Harbor, WA 98332

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)(A). 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:

Kable Bo Davis, Product Manager 03
 Invertebrate & Vertebrate Branch 1, Registration Division (7505P)

Date:

10/4/16

2. This registration is time-limited and expires 10/04/2018.
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 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.

- A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats 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 cat incidents for each severity code for each pet weight range on the product label, as applicable.
- 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, as applicable.
- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats 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
GDCI-129121-152

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. 91300-6.”
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 CSF:

- Basic CSF dated 11/20/2015

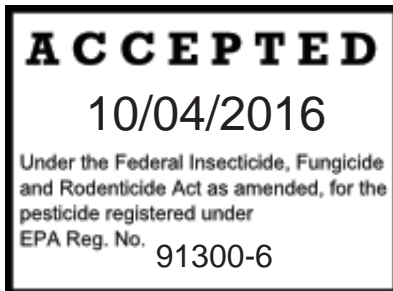
If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Enclosure

Primary brand name: Promika ZoGuard Plus for Cats

Alternate Brand Name:

Sublabel 1: Promika ZoGuard Plus for Cats Spot-On Sublabel 2: Promika ZoGuard Plus for Cats Spot-On {single applicator}
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Sublabel 1: Promika ZoGuard Plus for Cats Spot-On

[text in [] denotes optional language]

{text in {} denotes location of text on packaging, notes to reviewer, text that will not be on final label}

(text in () appears on label)

{Front Panel of Carton}

Promika ZoGuard Plus for Cats

{The word “Cats” in the product name will be 75% of the height of the largest letter in the primary brand name.}

{One of the following statements will appear on the front panel.}

- Use ONLY on Cats & Kittens Weighing over 1.5 lbs. & Over 8 Weeks old *{OR}*
- Use ONLY on Cats and Kittens Weighing over 1.5 lbs. & Over 8 Weeks old *{OR}*
- ONLY For Cats and Kittens Older Than 8 Weeks & Weighing Over 1.5 lbs. *{OR}*
- ONLY For Cats & Kittens Older Than 8 Weeks & Weighing Over 1.5 lbs. *{OR}*
- ONLY For Cats and Kittens Older Than 8 Weeks and Weighing Over 1.5 lbs. *{OR}*
- ONLY For Cats & Kittens Older Than 8 Weeks and Weighing Over 1.5 lbs.

{Optional Marketing Claim}

[[3][6][12] Month Supply]

{When used, all three optional statements below will appear together.}

[Contains Fipronil and (S)-Methoprene, the active ingredients used in FRONTLINE® Plus for Cats]

[Frontline is a registered trademark of Merial]

[(Brand Name) is not manufactured or distributed by Merial, seller of Frontline® Plus for Cats]

{See optional graphics –on page 10 of this label that may or may not appear on front panel of carton}

{The front panel will have a large, clear picture of a cat in the weight range for the product as packaged.}

ACTIVE INGREDIENTS:

Fipronil..... 9.80%

(S)-Methoprene.....11.80%

OTHER INGREDIENTS:..... 78.40%

TOTAL 100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Back Panel for Precautionary Statements and First Aid

See Side Panel for Storage and Disposal

See inside panels and insert for additional Directions for Use

Net Contents: X fl oz [(mL)] [Y – 0.017 fl oz (0.50 mL) applicator(s)]

[3][Three] [6][Six] [12][Twelve]

{BACK PANEL of Carton}

Promika ZoGuard Plus for Cats

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

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

[Formulated in the USA]

[Manufactured For][Distributed By]:

Promika, LLC.

501 Cascade Pointe Lane, Suite 102

Cary, NC 27513

EPA Reg. No. 91300-XX

EPA Est. No. XXXX-XXX-XXX

READ ENTIRE LABEL BEFORE EACH USE

{One of these statements will be used}

USE ONLY ON CATS AND KITTENS WEIGHING OVER 1.5 LBS. & OVER 8 WEEKS OF AGE {OR}

USE ONLY ON CATS AND KITTENS WEIGHING OVER 1.5 LBS. AND OVER 8 WEEKS OF AGE

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 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 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 Poison Control Center or doctor for treatment advice.
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 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. For emergency medical treatment information, you may contact SafetyCall at 1-844-685-9173 seven days a week, 24-hours a day.	

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. Do not use on rabbits or animals other than cats.

{The following text in a box will be placed in the lower right hand corner of back panel.}

Side Effects (Cats): 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. In some cases, gastrointestinal signs such as vomiting or diarrhea may occur. If these or other side effects occur consult your veterinarian or call SafetyCall at 1-844-685-9173. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application.

FREQUENCY OF APPLICATION

[Use [Brand name][this product] monthly for control of fleas, ticks [and] chewing lice [and mosquitos] . [Studies show that] [Brand name] [this product] kills adult fleas, flea eggs, and flea larvae and prevents development of all flea stages for up to six weeks. Apply monthly if your cat is at high risk for flea reinfestation[, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand name][This product] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Avoid contact with treated area until dry. Do not reapply for [30 days] [4 weeks]. [[Brand name][This product] can be used on breeding, pregnant and lactating [queens] [female cats].]

[Brand Name] [This product] may be applied once every [30 days] [4 weeks] [month].

Treatment remains effective, even after bathing, water immersion, or exposure to sunlight. Do not reapply [Brand Name] for 30 days [4 weeks] [1 month].]

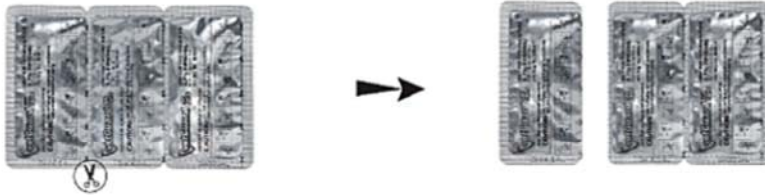
{Begin Package Insert}

Promika ZoGuard Plus for Cats

How to Open:

REMOVE AND OPEN PACKAGE

1. Cut along scissor cut line to separate unit



2. Turn unit over and cut corner at bulb end



3. From cut corner, peel backing completely off from bottom to top



4. Remove the applicator



OPEN APPLICATOR

Hold upright with foil side away from you and snap applicator tip back to open.

{End Package Insert}

{Inside Carton Panels}

Promika ZoGuard Plus for Cats

{One of the following statements will appear on the inside carton panel.}

Use ONLY on Cats & Kittens Weighing over 1.5 lbs. & Over 8 Weeks old {OR}
Use ONLY on Cats and Kittens Weighing over 1.5 lbs. & Over 8 Weeks old {OR}
ONLY For Cats and Kittens Older Than 8 Weeks & Weighing Over 1.5 lbs. {OR}
ONLY For Cats & Kittens Older Than 8 Weeks & Weighing Over 1.5 lbs. {OR}
ONLY For Cats and Kittens Older Than 8 Weeks and Weighing Over 1.5 lbs. {OR}
ONLY For Cats & Kittens Older Than 8 Weeks and Weighing Over 1.5 lbs.

How to Open

Refer to package insert on directions on how to open package.

How to Apply:

Remove applicator[s] from packaging. Using one applicator, hold the applicator with the narrow end pointing up. [Snap the outline of the tip back to allow access to the [dotted tip] [applicator]]. {OR}
[Snap the applicator tip [backwards] across the marked line] [to allow access to the] [dotted tip] [notches][applicator]]. Holding applicator away from your and your cat's eyes snap the applicator tip [at notched line] to open.] Apply [this product] at a spot between the cat's shoulder blades. Part the hair and place the open end of the applicator just above the skin. Squeeze the entire contents of the applicator and direct the solution in one spot and onto the cat's skin. Allow the area to dry. Use only one applicator per treatment.

Restrictions

Do not apply more frequently than once every 4 weeks.
Be sure your cat is dry before application and keep your cat dry for 24 hours after application.
Do not allow your cat to ingest this product.
Do not use on kittens under 8 weeks of age.
Do not apply to cats weighing less than 1.5 lbs.
Do not double-dose cats.
Use entire contents of applicator on each cat. [Do not split one applicator between two cats.]
Do not apply more than one applicator per treatment for one cat regardless of the cat's weight.
Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

[Optional pictogram]



[Manufactured For][Distributed By]:

Promika, LLC.
501 Cascade Pointe Lane, Suite 102
Cary, NC 27513

EPA Reg. No. 91300-XX
EPA Est. No. XXXX-XXX-XXX

[WARRANTY] [LIMITATION OF WARRANTY AND LIABILITY]

[IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse),

the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of [Company]. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, [Company] makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither [Company], the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. 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, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.]

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

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

[Formulated in the USA]

[Manufactured For][Distributed By]:

Promika, LLC.

501 Cascade Pointe Lane, Suite 102

Cary, NC 27513

EPA Reg. No. 91300-XX

EPA Est. No. XXXX-XXX-XXX

{SIDE PANEL 1}

[[Brand name]][This product]. Three month supply. ONLY for Cats & Kittens 8 Weeks and Older and Over 1.5 lb.

{SIDE PANEL 2}

[[Brand name]][This product]. ONLY for Cats & Kittens 8 Weeks and Older and Over 1.5 lb.

{SIDE PANEL 3}

[[Brand name]][This product]. ONLY for Cats & Kittens 8 Weeks and Older and Over 1.5 lb.

STORAGE AND DISPOSAL

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

[Optional recycling graphic]



{SIDE PANEL 4}

[[Brand name]][This product]. ONLY for Cats & Kittens 8 Weeks and Older and Over 1.5 lb.

[BAR CODE AREA]

[Lot code; only number will appear]

{APPLICATOR LABEL}

Promika ZoGuard Plus for Cats Only for cats over 8 weeks old and weighing over 1.5 lbs. Fipronil 9.8%, (S)-methoprene 11.8% 0.017 fl. oz. [0.5 ml] EPA Reg. No. 91300-XX Lot/Batch No. {only number will appear}	KEEP OUT OF REACH OF CHILDREN CAUTION: Read accompanying label before use.
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{OUTER BLISTER LABEL}

Promika ZoGuard Plus for Cats Only for cats over 8 weeks old and weighing over 1.5 lbs Fipronil 9.8%, (S)-methoprene 11.8% 0.017 fl oz [(0.5 ml)] EPA REG. No. 91300-XX Lot/Batch No. {only number will appear}	KEEP OUT OF REACH OF CHILDREN CAUTION. For external use only. Read accompanying label before use.
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{IMAGE FOR OUTER BLISTER LABEL}



{Optional Marketing Claims}

For use ONLY on cats & kittens weighing over 1.5 lbs and over 8 weeks of age
Only for cats [&] [and] kittens over 8 weeks of age and weighing over 1.5 lbs
Apply to kittens over 8 weeks old and weighing over 1.5 lbs.
Apply to kittens 8 weeks or older and weighing over 1.5 lbs.

Mosquitoes

Kills mosquitoes [within 24 hours for up to 14 days and within 48 hours for up to 28 days]

Chewing Lice

Kills chewing lice
Rapid elimination of chewing lice infestation

Adult Fleas

Kills adult fleas [for up to six weeks]
Kills Fleas [Up to [4][6] weeks]!
Kills fleas which may be a source of flea allergy dermatitis

Ticks

Kills ticks including those that may transmit Lyme disease
Kills Ticks for Up to [4 weeks] [1 month] [30 days]!
Kills Deer Ticks [that may carry Lyme disease] for up to [4 weeks] [1 month] [30 days]
Kills [brown dog ticks [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks][,][and deer ticks] [for up to [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 weighing 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 flea, tick, [mosquito,] chewing lice, and flea egg protection
Monthly flea, tick, [mosquito] and chewing lice protection
Kills fleas, ticks, [mosquitoes,] flea eggs, and chewing lice
[Seven][7] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae
[Six][6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae
[Six][6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs & flea larvae
[Five][5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs & flea larvae
[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 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 up to [4 weeks] [1 month] [30 days]!
Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [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 over 8 weeks of age and weighing over 1.5 lbs.

Flea Eggs and Larvae

Controls flea reinfestation on your cat [for up to six weeks]

Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae [for up to six weeks]
Kills all stages of the flea [adult fleas, flea eggs, flea larvae] and prevents the development of flea pupae
If cat is at high risk for flea reinfestation apply once a month
Kills flea eggs [larvae] [and prevents the development of pupae] for up to six weeks
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
Kills Flea Eggs & Flea Larvae [for up to six weeks]!
Prevents Flea Eggs From Developing Into Biting Adults


























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 and older and weighing over 1.5 lbs.
Fast Acting
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!]
[Three Applications][Six Applications][Twelve Applications]
[3 Month Supply][6 Month Supply][12 Month Supply]
Waterproof
Effective even after bathing
Effective after bathing and exposure to water and sunlight
Can be used on breeding, pregnant and lactating [queens], [female] [cats]
[3][6][12][Applications]
Controls and prevents infestation of listed pests for [4 weeks][1 month]
Lift [here] for more information

{When used, all three optional statements will appear together.}

Contains Fipronil and (S)-Methoprene, the active ingredients used in Frontline® Plus For Cats
Frontline is a registered trademark of Merial
(Brand Name) is not manufactured or distributed by Merial, seller of Frontline® Plus for Cats

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

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	

Sublabel 2: Promika ZoGuard Plus for Cats Spot-On {single applicator}

[text in [] denotes optional language]

{text in {} denotes location of text on packaging, notes to reviewer, text that will not be on final label}

(text in () appears on label)

{Front Panel of Foil-Lined Pouch; package is single applicator in foil-lined pouch}

Promika ZoGuard Plus for Cats

{The word “Cats” in the product name will be 40% of the height of the largest letter in the primary brand name due to the small package size.}

{One of the following statements will appear on the front panel.}

Use ONLY on Cats & Kittens Weighing Over 1.5 lbs. & Over 8 Weeks Old {OR}

Use ONLY on Cats and Kittens Weighing over 1.5 lbs. & Over 8 Weeks old {OR}

ONLY For Cats and Kittens, Older than 8 Weeks & Weighing Over 1.5 lbs. {OR}

ONLY For Cats & Kittens Older Than 8 Weeks & Weighing Over 1.5 lbs. {OR}

ONLY For Cats and Kittens Older Than 8 Weeks and Weighing Over 1.5 lbs. {OR}

ONLY For Cats & Kittens Older Than 8 Weeks and Weighing Over 1.5 lbs.

{Optional Marketing Claim}

[1 Month Supply]

{When used, all three optional statements below will appear together.}

[Contains Fipronil and (S)-Methoprene, the active ingredients used in FRONTLINE® Plus for Cats]

[Frontline is a registered trademark of Merial]

[(Brand Name) is not manufactured or distributed by Merial seller of Frontline® Plus for Cats]

{See optional graphics on page 19 of this label that may or may not appear on front panel of carton}

{The front panel will have a large, clear picture of a cat in the weight range for the product as packaged.}

ACTIVE INGREDIENT:

Fipronil..... 9.80%

(S)-Methoprene.....11.80%

OTHER INGREDIENTS:.....78.40%

TOTAL 100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Back Panel for Precautionary Statements and First Aid

See Package Insert for Complete Directions for Use and Storage and Disposal

Net Contents: 0.17 fl oz [(mL)] [[1][One] – 0.017 fl oz (0.50 mL) applicator]

[1][One] [Application]

{BACK PANEL OF FOIL-LINED POUCH}

Promika ZoGuard Plus for Cats

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

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

[Formulated in the USA]

[Manufactured For][Distributed By]:

Promika, LLC.

1204 Village Market Place, #273

Morrisville, NC 27560

EPA Reg. No. 91300-XX

EPA Est. No. XXXX-XXX-XXX

READ ENTIRE LABEL BEFORE EACH USE

{One of these statements will be used}

**USE ONLY ON CATS AND KITTENS WEIGHING OVER 1.5 LBS. & OVER 8 WEEKS OF AGE {OR}
USE ONLY ON CATS AND KITTENS WEIGHING OVER 1.5 LBS. AND OVER 8 WEEKS OF AGE**

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 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 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 Poison Control Center or doctor for treatment advice.
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 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. For emergency medical treatment information, you may contact SafetyCall at 1-844-685-9173 seven days a week, 24-hours a day.

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. Do not use on rabbits or animals other than cats.

{The following text in a box will be placed in the lower right hand corner of back panel.}

Side Effects (Cats): 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. In some cases, gastrointestinal signs such as vomiting or diarrhea may result. If these or other side effects occur consult your veterinarian or call SafetyCall at 1-844-685-9173. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application.

[BAR CODE AREA]

[Lot code; only number will appear]

{Begin Foil-Line Pouch Insert}

Promika ZoGuard Plus for Cats

{One of the following statements will appear on the insert.}

Use ONLY on Cats & Kittens Weighing over 1.5 lbs. & Over 8 Weeks old *{OR}*
Use ONLY on Cats and Kittens Weighing over 1.5 lbs. & Over 8 Weeks old *{OR}*
ONLY For Cats and Kittens Older Than 8 Weeks & Weighing Over 1.5 lbs. *{OR}*
ONLY For Cats & Kittens Older Than 8 Weeks & Weighing Over 1.5 lbs. *{OR}*
ONLY For Cats and Kittens Older Than 8 Weeks and Weighing Over 1.5 lbs. *{OR}*
ONLY For Cats & Kittens Older Than 8 Weeks and Weighing Over 1.5 lbs.

ACTIVE INGREDIENT:

Fipronil..... 9.80%
(S)-Methoprene..... 11.80%

OTHER INGREDIENTS:..... 78.40%
TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

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 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 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 Poison Control Center or doctor for treatment advice.
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 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. For emergency medical treatment information, you may contact SafetyCall at 1-844-685-9173 seven days a week, 24-hours a day.

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. Do not use on rabbits or animals other than cats.

Side Effects (Cats): 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. In some cases, gastrointestinal signs such as vomiting or diarrhea

may occur. If these or other side effects occur consult your veterinarian or call SafetyCall at 1-844-685-9173. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application.

FREQUENCY OF APPLICATION

[Use [Brand name][this product] monthly for control of fleas, ticks [and] chewing lice [and mosquitos]. [Studies show that] [Brand name] [this product] kills adult fleas, flea eggs, flea larvae and prevents development of all flea stages for up to six weeks. Apply monthly if your cat is at high risk for flea reinfestation[, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand name][This product] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Avoid contact with treated area until dry. Do not reapply for [30 days] [4 weeks]. [[Brand name][This product] can be used on breeding, pregnant and lactating [queens] [female cats].]

[Brand Name] [This product] may be applied once every [30 days] [4 weeks] [month].

Treatment remains effective, even after bathing, water immersion, or exposure to sunlight. Do not reapply [Brand Name] for 30 days [4 weeks] [1 month].]

How to Open:

1 Fold back the safety tab



2 Cut with scissors to open applicator

How to Apply:

Remove applicator from packaging. Using one applicator, hold the applicator with the narrow end pointing up.

[Cut] the applicator tip across the marked line [to allow access to the] [dotted tip] [notches][applicator]]. {OR}

[Holding applicator away from your and your cat's eyes, cut the applicator tip [at notched line] to open.]

Apply [this product] at a spot between the cat's shoulder blades. Part the hair and place the open end of the applicator just above the skin. Squeeze the entire contents of the applicator and direct the solution in one spot and onto the cat's skin. Allow the area to dry. Use only one applicator per treatment.

Restrictions

Do not apply more frequently than once every 4 weeks.

Be sure your cat is dry before application and keep your cat dry for 24 hours after application.

Do not allow your cat to ingest this product.

Do not use on kittens under 8 weeks of age.

Do not apply to cats weighing less than 1.5 lbs.

Do not double-dose cats.

Use entire contents of applicator on each cat. [Do not split one applicator between two cats.]

Do not apply more than one applicator per treatment for one cat regardless of the cat's weight.

Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

[Optional pictogram]



[WARRANTY]

[LIMITATION OF WARRANTY AND LIABILITY]

[IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of [Company]. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, [Company] makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither [Company], the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. 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, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.]

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

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

[Formulated in the USA]

[Manufactured For][Distributed By]:

Promika, LLC.

1204 Village Market Place, #273

Morrisville, NC 27560

EPA Reg. No. 91300-XX

EPA Est. No. XXXX-XXX-XXX

STORAGE AND DISPOSAL

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

[Optional recycling graphic]



{End Foil Lined Pouch Insert}

{APPLICATOR LABEL}

Promika ZoGuard Plus for Cats Only for cats over 8 weeks old and weighing over 1.5 lbs Fipronil 9.8%, (S)-methoprene 11.8% 0.017 fl. oz. [(0.5 ml)] EPA Reg. No. 91300-XX Lot/Batch No. {only number will appear}	KEEP OUT OF REACH OF CHILDREN CAUTION: Read accompanying label before use.
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{OUTER BLISTER LABEL}

Promika ZoGuard Plus for Cats Only for cats over 8 weeks old and weighing over 1.5 lbs Fipronil 9.8%, (S)-methoprene 11.8% 0.017 fl oz [(0.5 ml)] EPA REG. No. 91300-XX Lot/Batch No. {only number will appear}	KEEP OUT OF REACH OF CHILDREN CAUTION. For external use only. Read accompanying label before use.
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{Optional Marketing Claims}

For use ONLY on cats & kittens weighing over 1.5 lbs and over 8 weeks of age
Only for cats [&] [and] kittens over 8 weeks of age and weighing over 1.5 lbs
Apply to kittens over 8 weeks old and weighing over 1.5 lbs.
Apply to kittens 8 weeks or older and weighing over 1.5 lbs.

Mosquitoes]

Kills mosquitoes [within 24 hours for up to 14 days and within 48 hours for up to 28 days]

Chewing Lice

Kills chewing lice
Rapid elimination of chewing lice infestation

Adult Fleas

Kills adult fleas [for up to six weeks]
Kills Fleas [Up to [4][6] weeks]!
Kills fleas which may be a source of flea allergy dermatitis

Ticks]

Kills ticks including those that may transmit Lyme disease
Kills Ticks for Up to [4 weeks] [1 month] [30 days]!
Kills Deer Ticks [that may carry Lyme disease] for up to [4 weeks] [1 month] [30 days]
Kills [brown dog ticks [(*Rhipicephalus sanguineus*)]] [American dog ticks,] [and] [lone star ticks],[,][and deer ticks] [for up to [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 weighing 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 flea, tick, [mosquito,] chewing lice, and flea egg protection
Monthly flea, tick, [mosquito] and chewing lice protection
Kills fleas, ticks, [mosquitoes,] flea eggs, and chewing lice
[Seven][7] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae][Six] [6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae
[Six][6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs & flea larvae
[Five][5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs & flea larvae
[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 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 up to [4 weeks] [1 month] [30 days]!
Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [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 over 8 weeks of age and weighing over 1.5 lbs.

Flea Eggs and Larvae


























Controls flea reinfestation on your cat [for up to six weeks]

Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae [for up to six weeks]
Kills all stages of the flea [adult fleas, flea eggs, flea larvae] and prevents the development of flea pupae
If cat is at high risk for flea reinfestation apply once a month
Kills flea eggs [larvae] [and prevents the development of pupae] for up to six weeks
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
Kills Flea Eggs & Flea Larvae [for up to six weeks]!
Prevents Flea Eggs From Developing Into Biting Adults

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 and older and weighing over 1.5 lbs.
Fast Acting
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]!
Waterproof
Effective even after bathing
Effective after bathing and exposure to water and sunlight
Can be used on breeding, pregnant and lactating [queens], [female] [cats]
1 Application
Controls and prevents infestation of listed pests for [4 weeks][1 month]
Lift [here] for more information
{When used, all three optional statements will appear together.}
Contains Fipronil and (S)-Methoprene, the active ingredients used in Frontline® Plus For Cats
Frontline is a registered trademark of Merial
(Brand Name) is not manufactured or distributed by Merial

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

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	