



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 4, 2018

Ann M. Tillman
Agent for Promika, LLC
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig harbor, WA 98332

Subject: Label Amendment – Modification of CRP packages
Product Name: PROMIKA ZOGUARD PLUS FOR CATS
EPA Registration Number: 91300-6
Application Date: 4-Aug-2017
Decision Number: 532225

Dear Ms. Tillman,

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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EPA Reg. No. 91300-6
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with FIFRA section 6. 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.

Sincerely,

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

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

Enclosure

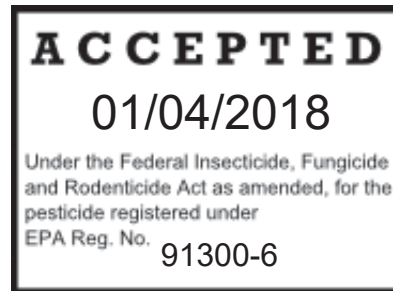
Primary brand name: Promika ZoGuard Plus for Cats

Alternate Brand Name: Fortress Defense for Cats

Heritage Plus for Cats

Sublabel 1: Promika ZoGuard Plus for Cats {Two alternate child resistant package types are included: the current approved CPR is described as an applicator inside a CRP blister and sold as a 3-count (strip of 3 applicators). The alternate CRP being added is described as a CRP blister applicator and is supplied as a 3 count and a 4 count or as multiples of 3- and 4- counts}

Sublabel 2: Promika ZoGuard Plus for Cats {single applicator. This alternate CRP is described as a CRP blister applicator and is supplied as a single applicator (1-count) in a foil pouch.}



Sublabel 1: Promika ZoGuard Plus for Cats [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
[Alternate brand name: Fortress Defense for Cats; Heritage 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]

[4][8][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 pages 9-10 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)]

[3][Three] [6][Six] [12][Twelve] [applicators each containing 0.017 fl oz (0.50 mL)]

[4][Four] [8][Eight] [12][Twelve] [applicators each containing 0.017 fl oz (0.50 mL)]

{End Front Panel of Carton}

{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.

5000 CentreGreen Way, Suite 100

Cary, NC 27513]

EPA Reg. No. 91300-6

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. This product is not a substitute for prescribed Heartworm preventative.

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 Side Effects 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.

PRODUCT INFORMATION

[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][1 month]. [[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].]

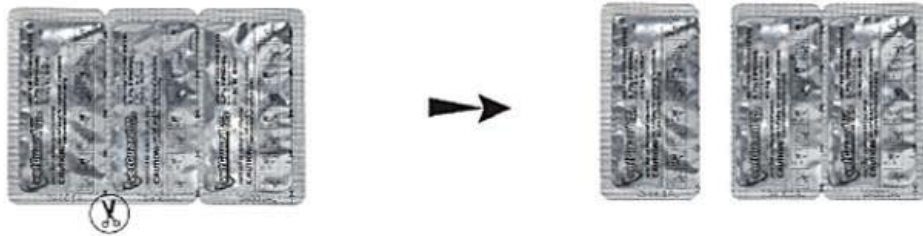
{END BACK PANEL of Carton}

{Begin Package Insert for applicator inside the CRP blister (3-Count).}

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.

{Begin Package insert for alternate CRP blister applicator (3-Count)}

1 Tear through perforation



2 Fold back the safety tab



3 Cut with scissors to open applicator



{Begin Package insert for alternate CRP blister applicator (4-Count)}

1 Tear through perforation



2 Fold back the safety tab



3 Cut with scissors to open applicator



{End Package Insert}

{Inside Carton Panels or Continuation of Package Insert for Cartons without Inside 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.

[[Brand Name] [This product] contains Fipronil and (S)-Methoprene [insect growth regulator] [IGR] to effectively kill fleas and ticks. [The active ingredients in [Brand Name][This product] features a formula developed for fast acting [and long lasting for up to [4 weeks][30 days][1 month]] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on cats.]

{Text below is only for Inside Carton Panels}

How to Open

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

{Remaining text below is for Inside Carton Panels and for Package Insert for Cartons without Inside Panels}

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 [30 days][4 weeks][1 month].
Be sure your cat is dry before application and keep your cat dry for 24 hours after application.
Do not bathe your cat 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 one 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.
5000 CentreGreen Way, Suite 100
Cary, NC 27513]

EPA Reg. No. 91300-6
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.
5000 CentreGreen Way, Suite 100
Cary, NC 27513]

EPA Reg. No. 91300-6
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 Inside Carton Panels or Package Insert for Cartons without Inside Panels }

{SIDE PANEL 1}

[[Brand name][This product]. [Three][Four][Six][Eight][Twelve] 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.

{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 - for applicator inside the CRP blister and for the CRP blister applicator}

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. 91300-6 Lot/Batch No. {only number will appear}	KEEP OUT OF REACH OF CHILDREN CAUTION: Read accompanying label before use.
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{End Applicator Label – for applicator inside the CRP blister and for the CRP blister applicator}

{OUTER BLISTER LABEL - for applicator inside the CRP blister}

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. 91300-6 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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{End Outer Blister Label – for applicator inside the CRP blister}

{IMAGE FOR OUTER BLISTER LABEL - for applicator inside the CRP blister}



{End Image for Outer Blister Label – for applicator inside the CRP blister}

{Optional Marketing Claims}

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

Mosquitoes

5. Kills mosquitoes [within 48 hours for up to 28 days]

Chewing Lice

6. Kills chewing lice
7. Rapid elimination of chewing lice infestation

Adult Fleas

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

Ticks

11. Kills ticks including those that may transmit Lyme disease
12. Kills Ticks for Up to [4 weeks] [1 month] [30 days]!
13. Kills Deer Ticks [that may carry Lyme disease] for up to [4 weeks] [1 month] [30 days]
14. 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]]
15. Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!

Multiple Infestations



























16. Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older and weighing over 1.5 lbs
17. Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]
18. Kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [and] flea larvae [and prevents the development of flea pupae]
19. Breaks the Flea Life Cycle
20. Monthly protection from flea, tick, [mosquito,] chewing lice, and flea egg
21. Monthly protection from flea, tick, [mosquito] and chewing lice
22. Kills fleas, ticks, [mosquitoes,] flea eggs, and chewing lice
23. [Seven][7] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae
24. [Six][6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae
25. [Six][6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs & flea larvae
26. [Five][5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs & flea larvae
27. [4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!
28. [[Four] [4] Week] [1 month] Flea, Tick, [Mosquito] and Chewing Lice Control
29. Use [Brand name][this product] monthly to break the flea life cycle.
30. [[Four][4] Week] [1 month] [30 day] Flea, Tick and Chewing Lice Control
31. Use [Brand name][This product] monthly to control ticks and chewing lice
32. Monthly protection from flea, tick, [mosquito,] flea egg, flea larvae and chewing lice.
33. [4 week] [1 month] [30 day] Flea and Tick Treatment!
34. Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]
35. Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!

36. Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [4 Weeks] [1 month] [30 days]
37. [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.
38. Flea Eggs and Larvae
39. Controls flea reinfestation on your cat [for up to six weeks]
40. Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae [for up to six weeks]
41. Kills all stages of the flea [adult fleas, flea eggs, flea larvae] and prevents the development of flea pupae
42. If cat is at high risk for flea reinfestation apply once a month
43. Kills flea eggs [larvae] [and prevents the development of pupae] for up to six weeks
44. With (S)-methoprene [Insect Growth Regulator] [IGR] which Breaks the Flea Life Cycle With (S)-methoprene to Break Flea Life Cycle
45. With [Insect Growth Regulator] [IGR] to Break Flea Life Cycle
46. Dual Action [!]: Fipronil with (S)-methoprene [insect growth regulator] [IGR] Effectively Breaks the Flea Life Cycle
47. Kills Flea Eggs & Flea Larvae [for up to six weeks]!
48. Prevents Flea Eggs From Developing Into Biting Adults

All Others

49. For Cats and Kittens 8 weeks of age or older and weighing over 1.5 lbs.
50. Can be used on kittens 8 weeks of age and older and weighing over 1.5 lbs.
51. Fast Acting
52. Easy to Use [Application]
53. Best if used year round!
54. Apply monthly
55. Once a month treatment
56. Apply once every [4 weeks] [month] [30 days]!
57. [4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
58. [Three Applications][Six Applications][Twelve Applications]
59. [3 Month Supply][6 Month Supply][12 Month Supply]
60. [Four Applications][Eight Applications][Twelve Applications]
61. [4 Month Supply][8 Month Supply][12 Month Supply]
62. Waterproof
63. Effective even after bathing
64. Effective after bathing and exposure to water and sunlight
65. Can be used on breeding, pregnant and lactating [queens], [female] [cats]
66. [3][6][12][Applications]
67. [4][8][12][Applications]
68. Controls and prevents infestation of listed pests for [4 weeks][1 month]
69. Lift [here] for more information
{When used, all three optional statements will appear together.}
70. Contains Fipronil and (S)-Methoprene, the active ingredients used in Frontline® Plus For Cats
71. Frontline is a registered trademark of Merial
72. (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 {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 Pouch; package is single applicator in heat sealed foil pouch}

Promika ZoGuard Plus for Cats

[Alternate brand name: Fortress Defense for Cats; Heritage 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 pages 18-19 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

See Package Insert for First Aid, and Complete Directions for Use

Net Contents: [0.17 fl oz [(mL)]

[[1][One] applicator containing – 0.017 fl oz (0.50 mL)]

[1][One] [Application]

{End Front Panel of Foil Pouch}

{BACK PANEL OF FOIL 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.

5000 CentreGreen Way, Suite 100

Cary, NC 27513]

EPA Reg. No. 91300-6

EPA Est. No. XXXX-XXX-XXX

READ ENTIRE PRODUCT LABEL INSIDE THE POUCH BEFORE EACH USE

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. This product is not a substitute for prescribed Heartworm preventative.

PRODUCT INFORMATION

[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][1 month]. [[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].]

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 Side Effects text in a box will be placed in the lower right hand corner of back panel.}

<p>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.</p>
--

[BAR CODE AREA]

[Lot code; only number will appear]

{End BACK PANEL of Foil Pouch}

{Begin Foil 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. This product is not a substitute for prescribed Heartworm preventative.

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.

PRODUCT INFORMATION

[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] [1 month]. [[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 [30 days][4 weeks][month].
Be sure your cat is dry before application and keep your cat dry for 24 hours after application.
Do not bathe your cat 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 one 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.

5000 CentreGreen Way, Suite 100

Cary, NC 27513]

EPA Reg. No. 91300-6

[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. 91300-6 Lot/Batch No. {only number will appear}	KEEP OUT OF REACH OF CHILDREN CAUTION: Read accompanying label before use.
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{End Applicator Label}

{Optional Marketing Claims}

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

Mosquitoes]

5. Kills mosquitoes [within 48 hours for up to 28 days]

Chewing Lice

6. Kills chewing lice
7. Rapid elimination of chewing lice infestation

Adult Fleas

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

Ticks]

11. Kills ticks including those that may transmit Lyme disease
12. Kills Ticks for Up to [4 weeks] [1 month] [30 days]!
13. Kills Deer Ticks [that may carry Lyme disease] for up to [4 weeks] [1 month] [30 days]
14. 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]]

15. Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!

Multiple Infestations]

16. Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older and weighing over 1.5 lbs.
17. Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]
18. Kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [and] flea larvae [and prevents the development of flea pupae]
19. Breaks the Flea Life Cycle
20. Monthly protection from flea, tick, [mosquito,] chewing lice, and flea egg
21. Monthly protection from flea, tick, [mosquito] and chewing lice
22. Kills fleas, ticks, [mosquitoes,] flea eggs, and chewing lice
23. [Seven][7] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae]
24. [Six][6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs, flea larvae and prevents the development of flea pupae
25. [Six][6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, mosquitoes, chewing lice, flea eggs & flea larvae
26. [Five][5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, chewing lice, flea eggs & flea larvae
27. [4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!
28. [[Four][4] Week] [1 month] Flea, Tick, [Mosquito] and Chewing Lice Control
29. Use [Brand name][this product] monthly to break the flea life cycle.
30. [[Four][4] Week] [1 month] [30 day] Flea, Tick and Chewing Lice Control
31. Use [Brand name][This product] monthly to control ticks and chewing lice
32. Monthly protection from flea, tick, [mosquito,] flea egg, flea larvae and chewing lice.]
33. [[4 week] [1 month] [30 day] Flea and Tick Treatment!
34. Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]
35. Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!
36. Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [4 Weeks] [1 month] [30 days]
37. [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


























38. Controls flea reinfestation on your cat [for up to six weeks]
39. Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae [for up to six weeks]
40. Kills all stages of the flea [adult fleas, flea eggs, flea larvae] and prevents the development of flea pupae
41. If cat is at high risk for flea reinfestation apply once a month
42. Kills flea eggs [larvae] [and prevents the development of pupae] for up to six weeks
43. With (S)-methoprene [Insect Growth Regulator] [IGR] which Breaks the Flea Life Cycle
44. With (S)-methoprene to Break Flea Life Cycle
45. With [Insect Growth Regulator] [IGR] to Break Flea Life Cycle
46. Dual Action [!]: Fipronil with (S)-methoprene [insect growth regulator] [IGR]
47. Effectively Breaks the Flea Life Cycle
48. Kills Flea Eggs & Flea Larvae [for up to six weeks]!
49. Prevents Flea Eggs From Developing Into Biting Adults

All Others

50. For Cats and Kittens 8 weeks of age or older and weighing over 1.5 lbs.
51. Can be used on kittens 8 weeks of age and older and weighing over 1.5 lbs.
52. Fast Acting
53. Easy to Use [Application]
54. Best if used year round!
55. Apply monthly
56. Once a month treatment
57. Apply once every [4 weeks] [month] [30 days]!
58. [4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
59. Waterproof
60. Effective even after bathing
61. Effective after bathing and exposure to water and sunlight
62. Can be used on breeding, pregnant and lactating [queens], [female] [cats]

- 63. 1 Application
- 64. Controls and prevents infestation of listed pests for [4 weeks][1 month]
- 65. Lift [here] for more information
- 66. {When used, all three optional statements will appear together.}
- 67. Contains Fipronil and (S)-Methoprene, the active ingredients used in Frontline® Plus For Cats Frontline is a registered trademark of Merial
- 68. (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	