

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 6, 2017

James McFadden, Ph.D.
Director, Regulatory Affairs
Wellmark International
1501 E. Woodfield Rd., Suite 200W
Schaumburg, IL 60173

Subject: Label Amendment – Correction of the lower limit for each dog size group at the

request of New York State.

Product Name: RF2164 A/T Combo EPA Registration Number: 2724-811 Application Date: October 11, 2017

Decision Number: 532755

#### Dear Dr. McFadden:

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

Page 2 of 2 EPA Reg. No. 2724-811 Decision No. 532755

with FIFRA section 6. If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

Michael Wagman, Acting Product Manager 4 Invertebrate and Vertebrate Branch 1

Registration Division (7505P)

Office of Pesticide Programs

Enclosure

Text within braces { } denotes notes to reviewer.
Text within brackets [ ] denotes optional language.
Text within parentheses ( ) is meant to be included on the label

## ACCEPTED

11/06/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 2724-811

#### RF2164 A/T COMBO

Alternate brand name: Vet-Kem® Ovitrol® X-Tend™ Flea & Tick Spot On® for Dogs (Toy 6-12 lbs., Small 13-31 lbs., Medium 32-55 lbs., Large 56-80 lbs., Extra Large 81 lbs. and over)

[Include "Dog" in product name and the Text for "Dog" must be at least 75% of the largest letter in the Brand Name]

Front Panel - For Use ONLY on [Toy (6-12 lbs.)], [Small (13-31 lbs.)], [Medium (32-55 lbs.)], [Large (56 - 80 lbs.)], and [Extra Large (81 lbs. and over)] Dogs/Puppies (10 Weeks of age or older)

Front Panel - For Use ONLY on Dogs/Puppies Weighing Over [6 lbs][13 lbs] [32 lbs] [56 lbs] [81 lbs]),{ as appropriate for package size} & 10 Weeks of age or older [Flea & Tick [& Mosquito][Treatment] [and] Control]
Spot-On Flea & Tick Control ONLY for Dogs/Puppies Weighing Over [6 lbs][13 lbs] [32 lbs] [56 lbs] [81 lbs]) {as appropriate for package size} & 10 Weeks of age or older

#### (Front panel)

#### **ACTIVE INGREDIENTS:**

Etofenprox	30.0%
S-Methoprene	
Piperonyl Butoxide*	
OTHER INGREDIENTS:	61.4%
TOTAL	100.0%

<sup>\*(</sup>butyl carbityl) (6-propylpiperonyl ether) and related compounds

## KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel for First Aid and Additional Precautionary Statements

#### **NET CONTENTS:**

[One][Three][Four][[Six] 0.05 fl oz (1.5 cc) [vial][tube][cartridge] (Toy Dogs (Over 6 lbs)/Puppies)(10 Weeks of Age or Older) [One][Three][Four][Six]0.10 fl oz (3.0 cc) [vial] [tube][cartridge] (Small Dogs/Puppies)/(10 Weeks of Age or Older) [One][Three][Four][Six]0.15 fl oz (4.5 cc) [vial][tube][cartridge] (Medium Dogs/Puppies)/ (10 Weeks of Age or Older) [One][Three][Four][Six]0.20 fl oz (6.0 cc) [vial][tube][cartridge] (Large Dogs/Puppies) (10 Weeks of Age or Older) [One][Three][Four][Six]0.30 fl oz (9.0 cc) [vial][tube][cartridge] (Extra Large Dogs) (10 Weeks of Age or Older)

EPA Reg. No. 2724-811

EPA Est. No. Lot/Batch No.:



{A 1.5cm x 1.5cm cat prohibition icon will be in a box in the lower right hand corner of the front panel in yellow with black images.}

#### SUBLABEL A - APPLICATOR DEVICE PACKAGE

# 1. DIRECTIONS FOR USE WITH APPLICATOR <RF2164 A/T COMBO>

#### {Back Panel}

<RF2164 A/T COMBO> prevents flea eggs from developing into adult fleas for up to [75 days][10 weeks][2.5 months]. <RF2164 A/T COMBO> also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

Effective flea & tick control for your dog/puppy.

<brand> provides flea and tick protection for dogs/puppies for up to 30-days – and protection from flea reinfestation for up to [75 days][10 weeks][2.5 months. That's because it doesn't just kill adult fleas and ticks, it also prevents reinfestation by knocking out flea eggs and larvae that could hatch later on. Plus, it kills and repels mosquitoes.

A unique, convenient applicator for you. The [brand] Applicator is specially designed to make applying flea and tick control easier, more precise -- and neater - than ever before. You simply insert the appropriate [brand] tube [vial][cartridge] for your dog/puppy into the applicator, close it and squeeze to apply. The applicator's ergonomic, contoured [shape][design] makes it easy to grip and a built-in fin [tip] [comb] helps to spread [part] the [your] dog's/puppy's hair to allow the liquid to more readily [better] reach [apply] the [to] [your dog's/puppy's] skin. The tube [vial][cartridge] is sealed inside, so you can be confident that the liquid goes onto your dog/puppy - and not your hand. Plus, if the applicator is laid down on a table, counter or other flat surface, it won't run out or drip.

**DIRECTIONS FOR USE**: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. FOR USE ONLY ON DOGS/PUPPIES 10 WEEKS OF AGE OR OLDER & GREATER THAN [6] [13] [32] [56] [81] {as appropriate for package size} POUNDS. DO NOT USE ON OTHER ANIMALS! Read and follow all directions and precautions on this product label. [If you choose to apply directly to dog without using the applicator device, read and follow the Directions for Use For Direct Application to Dog on this package.]

#### **USE RESTRICTIONS**

THIS PRODUCT IS FOR INDOOR USE ONLY.

Do Not Allow Children to Apply this Product.

Do not apply this product to puppies less than 10 weeks of age

Do not apply this product to animals other than dogs/puppies!

Do not apply this product to dogs/puppies weighing less than [6][13][32][56][81] lbs.

Do not allow your dog/puppy to ingest this product.

Do not apply more than one [tube][vial][cartridge] per treatment for one dog regardless of the dog's weight.

Do not reapply this product for 30 days unless retreatment is required, but not sooner than 8 days after the initial treatment.

Do not retreat more than once per month.

Do not use on cats.

Keep cats away from treated dogs/puppies for 24 hours.

If applied to a cat or ingested by a cat, contact your veterinarian.

<RF2164 A/T COMBO> works by application directly to the dog's/puppy's skin, not to the hair. When applying, use applicator device tip to push aside dog's/puppy's hair to allow direct application to the skin. Do not get this product in dog's/puppy's eyes or mouth. In addition, dog must be dry 24 hours prior to application and remain dry for 24 hours after application. {Note: Application now assumes one [tube][vial][cartridge] per dog/puppy per application}

The <RF2164 A/T COMBO> provides a unique applicator device that allows dog/puppy owners to treat their dogs/puppies more securely, and dispose of liquid cartridges [tubes][vials]with less mess.

{Note: Each package contains [cartridges]/[tubes]/[vials] for [1][3][4][6] applications}

#### {DFU Set No. 1}

FOR USE ONLY ON [TOY (6-12 LBS)], [SMALL (13-31 lbs.)], [MEDIUM (32-55 lbs.)], DOGS/PUPPIES (10 WEEKS OF AGE OR OLDER)

To apply the <RF2164 A/T COMBO> treatment, use one disposable liquid cartridge [tube][vial][for each application] with the applicator device.

#### 1. OPEN [icon]{Icon set #1}

Use finger scoop to lift open [color, e.g. green] door.

#### 2. LOAD [icon] (2 alternate statements)

- -[To Load, place tube [cartridge][vial] white side up into the open applicator with front of tube placed under tab on door]
- -[To Load, place tube [cartridge][vial] white side up into the [open] applicator with tip end of tube placed under [color][U-shaped] tab on door]

[Ensure that tube [cartridge][vial] fits securely in the applicator.]

#### 3. CLOSE [icon]

Gently close the [color, e.g. green] door [and] the tube will snap open.

#### 4. APPLY [icon]

The dog/puppy should be standing for easy application. To apply, use [front edge of applicator] [tip] to part hair and get next to dog's/puppy's skin.

{Alternate statement depending on dog size, toy, small, medium}

[Press [circle] [[round] thumb pad] on [color-green] door once at each of two] {(for Toy dogs (Over 6 lbs) or pupples(10 weeks of Age or Older)) ]

[Press [circle] [[round] thumb pad] on [color-green] door once at each of three] {( for Small Dogs (13-31 lbs.)/puppies (10 weeks of Age or Older))}

[Press [circle] [[round] thumb pad] on [color-green] door once at each of three] { (for Medium dogs (32-55 lbs.)/ puppies (10 weeks of Age or Older))}

{continuing} evenly placed spots between the shoulder to the base of the tail. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy. Do not spread <RF2164 A/T COMBO> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy,

brushing the dog/puppy 12-24 hours after treatment will help to distribute the material over the skin.

#### 5. DISPOSE [icon]

[When finished, hold applicator device over trash.] To dispose of empty tube, open [color, e.g. green]

door and drop empty tube into trash or offer for recycling if available. [Close applicator device door and store in original package.]

6. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days following the initial treatment. Do not retreat more than once per month.

{Note: Each package contains [cartridges]/[tubes]/[vials] for [1][3][4][6] application[s]}

# FOR USE ONLY ON [LARGE] (56 - 80 lbs.), [EXTRA LARGE] (81 lbs. and over) DOGS/PUPPIES (10 WEEKS OF AGE OR OLDER)

1 OPEN [icon]{Icon set #1}

Use finger scoop to lift open [color, e.g. green] door.

- 2. LOAD [icon] (2 alternate statements)
- -[To Load, place tube [cartridge][vial] white side up into the open applicator with front of tube placed under tab on door]
- -[To Load, place tube [cartridge][vial] white side up into the [open] applicator with tip end of tube placed under [color][U-shaped] tab on door]

[Ensure that tube [cartridge][vial] fits securely in the applicator.]

3. CLOSE [icon]

Gently close the [color, e.g. green] door [and] the tube will snap open.

4 APPLY [icon]

The dog should be standing for easy application. To apply, use [front edge of applicator][tip] to part hair and get next to dog's/puppy's skin. Press [circle] [[round] thumb pad] on [color][green] door [number-once] at each of four or five evenly placed spots between the shoulder to the base of the tail. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy. Do not spread <RF2164 A/T COMBO> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after treatment will help to distribute the material over the skin.

- 5 DISPOSE [icon]
  - [When finished, hold applicator device over trash.] To dispose of empty tube, open [color, e.g. green] door and drop empty tube into trash or offer for recycling if available. [Close applicator device door and store in original package.]
- 6 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days following the initial treatment. Do not retreat more than once per month.

[Note: Each package contains [cartridges]/[tubes]/[vials] for [1][3][4][6] application[s]]

<RF2164 A/T COMBO> is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with <RF2164 A/T COMBO> rapidly kills fleas and may reduce the incidence of this condition.] <RF2164 A/T COMBO> is water resistant and remains efficacious following exposure to rainfall or swimming.]

[TREATMENT SCHEDULE			
Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/puppy			
Dog's/Puppy's Name	First Treatment Date	Second Treatment Date (30 Days From 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased <RF2164 A/T COMBO> from: \_\_\_\_\_\_ NOTES:\_\_\_

Treatment table can be expanded based on package size. (6 months)]

**STORAGE and DISPOSAL: Pesticide Storage**: Keep this product in its tightly closed original container when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals. Liquid Cartridge [vial][tube]

Pesticide Disposal and Container Handling: If empty: Do not reuse cartridge [vial] [tube]. Place in trash or offer for recycling if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS - CAUTION

.Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation.

HAZARDS TO DOMESTIC ANIMALS. DO NOT USE ON DOGS/PUPPIES LESS THAN [6][13][32][56][81] LBS, , {as appropriate for package size} OR PUPPIES LESS THAN 10 WEEKS OF AGE. For External use on dogs and puppies only. This product is not a substitute for prescribed heartworm preventative. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your dog/puppy with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

Some dogs/puppies may experience hair loss or temporary skin irritation at the application site. If signs persist or become more severe, contact veterinarian immediately and report incident to company at 1-800-XXX-XXXX.

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 first 5 minutes, then continue rinsing
	Call a poison control center or doctor for treatment advice.
HOT L	<b>INE NUMBER</b> : Have the product container or label with you when calling a poison contro
center	or doctor or going for treatment. For additional information on this pesticide product
(includ	ling health concerns, medical emergencies or pesticide incidents), you may also call 1-800

#### **WARRANTY AND CONDITIONS OF SALE:**

XXX-XXXX 24 hours/day, 7 days/week.

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and

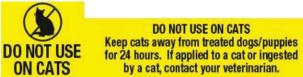
fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx or contact your veterinarian if your pet is experiencing an adverse event.

Wellmark International 1501 E. Woodfield Road. 200W Schaumburg, Illinois 60173 [zodiacpet.com] Made in USA

**Side Effects:** Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or [Brand name] at [phone number].

{A box labeled Side Effects will be immediately above the cat warning box on the back panel}



{A 1.5cm x 1.5cm cat prohibition icon and warning text in a box will be located at the lower right hand corner of the back panel in yellow with black images and text.}

#### {TEXT FOR LIQUID TUBE/CARTRIDGE/VIAL}

Product name
Etofenprox 30%, (S)-Methoprene 3.6%, Piperonyl Butoxide 5%
KEEP OUT OF REACH OF CHILDREN
CAUTION
READ ENTIRE LABEL BEFORE EACH USE.
EPA Reg. No. 2724-811
Net Contents [0.05 fl. oz. (1.5 cc)][0.10 fl. oz. (3.0 cc)][0.15 fl. oz. (4.5 cc)][0.20 fl. oz. (6.0 cc)][0.30 fl. oz. 9.0 cc)]



For Use Only on [Toy (6-12 lbs.)], [Small (13-31 lbs.)], [Medium (32-55 lbs.)], [Large (56 -80 lbs.)], and [Extra Large (81 lbs. and over)] Dogs/Puppies (10 Weeks of age or older)

# {Alternate Sets of ICONS for the <RF2164 A/T COMBO>} [ICON SET 1] [OPEN]



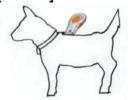
[LOAD]



[CLOSE]



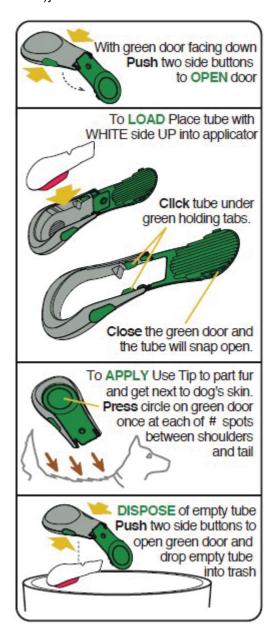
[APPLY]



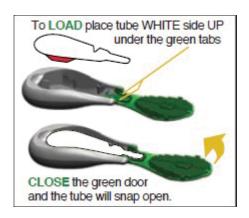
[DISPOSE]



**{ICON SET 2} {**ALTERNATE ICONS FOR DIRECTIONS FOR USE (will be specific to dog's/puppy's size)**}** 



({"#Spots" is a variable dependent on size – See Directions For Use) Door color may change based on brand. (Alternate LOAD icon)}



{ICON SET 3} {ALTERNATE ICONS FOR DIRECTIONS FOR USE (will be specific to dog's/puppy's size)}



{("#Spots" is a variable dependent on size – see Directions For USE) Door color may change based on brand.}

#### [2. DIRECTIONS FOR USE FOR DIRECT APPLICATION TO DOG/PUPPY]

#### **USE RESTRICTIONS**

THIS PRODUCT IS FOR INDOOR USE ONLY.

Do Not Allow Children to Apply this Product.

Do not apply this product to puppies less than 10 weeks of age.,

Do not apply this product to animals other than dogs or puppies!

Do not apply this product to dogs/puppies weighing less than [6][13][32][56][81] lbs. Do not allow your dog/puppy to ingest this product.

Do not apply more than one [tube][vial][cartridge] per treatment for one dog regardless of the dog's weight.

Do not reapply this product for 30 days unless retreatment is required, but not sooner than 8 days after the initial treatment.

Do not retreat more than once per month.

Do not use on cats.

Keep cats away from treated dogs/puppies for 24 hours.

If applied to a cat or ingested by a cat, contact your veterinarian.

<RF2164 A/T COMBO> works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin. Do not get this product in dog's/puppy's eyes or mouth. In addition, dog must be dry 24 hours prior to application and remain dry for 24 hours after application.

{Note: Application assumes one applicator per animal per application}

{Note: Each package contains [tubes]/[applicators] for [1][3][4][6] application[s]}

# FOR USE ONLY ON [TOY (6-12 LBS)][SMALL (13-31 lbs.)], [MEDIUM (32-55 lbs.)], DOGS/PUPPIES (10 WEEKS OF AGE OR OLDER)

- 1. [Bend at perforation and tear off first applicator [tube].]
- 2. [Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.]] Hold applicator [tube] upright and snap tip back, away from face and body.
- 3. The dog/puppy should be standing for easy application.
  {Alternate statements for Toy or Small, & Medium Dogs]
  [Apply <RF2164 A/T COMBO> evenly to two spots{toy dogs or puppies ( 6-12 lbs) 10 weeks of age or older)} on the top of the back from the shoulder to the base of the
  - [Apply <RF2164 A/T COMBO> evenly to three spots {(small (13-31 lbs.) or medium (32-55 lbs.) dogs/puppies (10 weeks of age or older))} on the top of the back from the shoulder to the base of the tail.]
  - At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
- 4. Do not spread <RF2164 A/T COMBO> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
- 5. Discard empty [tube][applicator] as described in Storage and Disposal
- 6. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days following the initial treatment. Do not retreat more than once per month.

{Note: Each package contains [tubes]/[applicators] for [1][3][4][6] application[s]}

#### **OPTIONAL GRAPHICS**







{# of spots is a variable dependent on dog size, see Directions For Use}

## FOR USE ONLY ON [LARGE] (56 - 80 lbs.), [EXTRA LARGE] (81 lbs. and over) DOGS/PUPPIES (10 WEEKS OF AGE OR OLDER)

- 1. [Bend at perforation and tear off first applicator [tube].]
- 2. [Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.]] Hold applicator [tube] upright and snap tip back, away from face and body
- 3. The dog/puppy should be standing for easy application. Apply <RF2164 A/T COMBO> evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
- 4. Do not spread <RF2164 A/T COMBO> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
- 5. Discard empty [tube][applicator] as described in Storage and Disposal
- 6. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days following the initial treatment. Do not retreat more than once per month.

#### **OPTIONAL GRAPHICS**







<RF2164 A/T COMBO> is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with <RF2164 A/T COMBO> rapidly kills fleas which may reduce the incidence of this condition. . [<RF2164 A/T COMBO> is water resistant and remains efficacious following exposure to rainfall or swimming.]

[TREATMENT SCHEDULE			
Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/puppy			
Dog's/Puppy's Name	First Treatment Date	Second Treatment Date (30 Days From 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased <RF2164 A/T COMBO> from:

NOTES.

Treatment table can be expanded based on package size. (6 months)]]

#### SUB-LABEL B FOR REFILLPACKAGE

(For use with applicator device or direct application to dog/puppy without applicator device)

(Front Panel)

#### <RF2164 A/T COMBO>

[Include "Dog" in product name and the Text for "Dog" must be at least 75% of the largest letter in Brand Name]

Front Panel - For Use Only on [Toy (6-12 lbs.)], [Small (13-31 lbs.)], [Medium (32-55 lbs.)], [Large (56 -80 lbs.)], and [Extra Large (81 lbs. and over)] Dogs/Puppies (10 Weeks of age or older)

#### [Flea & Tick [& Mosquito][Treatment] [and] Control]

Spot-On Flea & Tick Control ONLY for Dogs/Puppies (Over [6][13][32][56][81] lbs, {as appropriate for package size} and 10 Weeks of Age or Older

#### **ACTIVE INGREDIENTS:**

Etofenprox	30.0%
S-Methoprene (	3.6%
Piperonyl Butoxide *	5.0%
OTHER INGREDIENTS:	
TOTAL	100.0%

<sup>\*(</sup>butyl carbityl) (6-propylpiperonyl ether) and related compounds

## KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel for First Aid and Additional Precautionary Statements

EPA Reg. No. 2724-811 EPA Est No.

#### **NET CONTENTS:**

[One][Three][Four[][Six] 0.05 fl oz (1.5 cc) [vial][tube][cartridge] (Toy Dogs (Over 6 lbs)/Puppies)(10 Weeks of Age or Older) [One][Three][Four[][Six]0.10 fl oz (3.0 cc) [vial] [tube][cartridge] (Small Dogs/Puppies)/(10 Weeks of Age or Older) [One][Three][Four[][Six]0.15 fl oz (4.5 cc) [vial][tube][cartridge] (Medium Dogs/Puppies)/ (10 Weeks of Age or Older) [One][Three][Four[][Six]0.20 fl oz (6.0 cc) [vial][tube][cartridge] (Large Dogs/Puppies) (10 Weeks of Age or Older) [One][Three][Four[][Six]0.30 fl oz (9.0 cc) [vial][tube][cartridge] (Extra Large Dogs) (10 Weeks of Age or Older)



{A 1.5cm x 1.5cm cat prohibition icon will be in a box in the lower right hand corner of the front panel in yellow with black images.}

#### {Back Panel}

<RF2164 A/T COMBO> prevents flea eggs from developing into adult fleas for up to [75 days][10 weeks][2.5 months]. <RF2164 A/T COMBO> also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

[Effective flea & tick control for your dog/puppy.

<br/>
<br

[Note: full directions for use to be used if space allows]

**DIRECTIONS FOR USE**: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. FOR USE ONLY ON DOGS/PUPPIES WEIGHING OVER[6][13], [32,] [56], [81], {as appropriate for package size} LBS) AND 10 WEEKS OF AGE OR OLDER. DO NOT USE ON OTHER ANIMALS! Read and follow all directions and precautions on this product label.

[To apply the <RF2164 A/T COMBO> treatment with the [Brand Name] applicator, use one disposable liquid cartridge [tube][vial][for each application] with the applicator device.]

[Remove one refill [tube][cartridge][vial] from the package and insert into opened [brand name] applicator device. Make application according to label directions supplied with the [brand name] applicator device.] If you need directions for application, please call 1-800-XXX-XXXX.

[However, if you choose to apply directly to dog/puppy without using the applicator device, read and follow the Directions for Use For Direct Application to Dog /Puppy on this package.]

#### DIRECTIONS FOR USE FOR DIRECT APPLICATION TO DOG/PUPPY

#### **USE RESTRICTIONS**

THIS PRODUCT IS FOR INDOOR USE ONLY.

Do Not Allow Children to Apply this Product.

Do not apply this product to puppies less than 10 weeks of age.

Do not apply this product to animals other than dogs or puppies!

Do not apply this product to dogs/puppies weighing less than [6][13][32][56][81] lbs.

Do not allow your dog/puppy to ingest this product.

Do not apply more than one [applicator][tube] per treatment for one dog regardless of the dog's weight.

Do not reapply this product for 30 days unless retreatment is required, but not sooner than 8 days after the initial treatment.

Do not retreat more than 1 time per month.

Do not use on cats.

Keep cats away from treated dogs/puppies for 24 hours.

If applied to a cat or ingested by a cat, contact your veterinarian.

<RF2164 A/T COMBO> works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin. Do not get this product in dog's/puppy's eyes or mouth. In addition, dog must be dry 24 hours prior to application and remain dry for 24 hours after application.

{Note: Application assumes one applicator per animal per application} {Note: Each package contains [tubes]/[applicators] for [1][3][4][6] application[s]}

# FOR USE ONLY ON [TOY ( 6-12 LBS)][SMALL] (13-31 lbs.)], [MEDIUM] (32-55 lbs.)] DOGS/PUPPIES 10 WEEKS OF AGE OR OLDER

- 1. [Bend at perforation and tear off first applicator [tube].]
- 2. [Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.]] Hold applicator [tube] upright and snap tip back, away from face and body.
- The dog/puppy should be standing for easy application.
  {Alternate statements depending on dog size.
  [Apply <RF2164 A/T COMBO> evenly to two spots ({toy dogs/puppies}) on the top of the back from the shoulder to the base of the tail ]

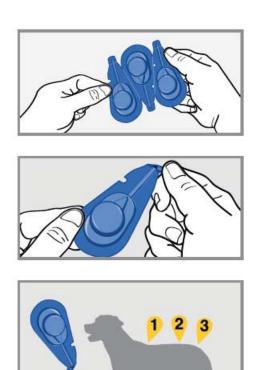
[Apply <RF2164 A/T COMBO> evenly to three spots {small or medium dogs/puppies} on the top of the back from the shoulder to the base of the tail. ]

At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.

- 4. Do not spread <RF2164 A/T COMBO> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin.
- 5. Discard empty [tube][applicator] as described in Storage and Disposal
- 6. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.

[Note: Each package contains [tubes]/[applicators] for [1][3][4][6] application[s]]

### {OPTIONAL GRAPHICS}

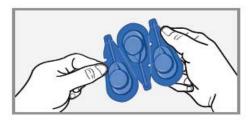


{# of spots is a variable dependent on dog size — See Directions For Use}

# FOR USE ONLY ON [LARGE] (56 - 80 lbs.), [EXTRA LARGE] (81 lbs. and over) DOGS/PUPPIES (10 WEEKS OF AGE OR OLDER)

- 1. [Bend at perforation and tear off first applicator [tube].]
- 2. [Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.]] Hold applicator [tube] upright and snap tip back, away from face and body
- 3. The dog/puppy should be standing for easy application. Apply <RF2164 A/T COMBO> evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
- 4. Do not spread <RF2164 A/T COMBO> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
- 5. Discard empty [tube][applicator] as described in Storage and Disposal
- 6. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.

#### **OPTIONAL GRAPHICS**







<RF2164 A/T COMBO> is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with <RF2164 A/T COMBO > rapidly kills fleas and prevents further flea bites. ] [<RF2164 A/T COMBO> is water resistant and remains efficacious following exposure to rainfall or swimming.]

[TREATMENT SCHEDULE Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/puppy			
Dog's/Puppy's Name	First Treatment Date		
Reminder: Lnurchased <re2164 a="" combo="" t=""> from:</re2164>			

Reminder:	I purchased <rf2164 a="" combo="" t=""></rf2164>	from:	
NOTES:			

Treatment table can be expanded based on package size. (6 months)]]

#### (Precautionary/First Aid and Storage/Disposal) text included)

#### WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx or contact your veterinarian if your pet is experiencing an adverse event.

Wellmark International 1501 East Woodfield Road 200W Schaumburg, Illinois 60173 [zodiacpet.com]

**Side Effects:** Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or [Brand name] at [phone number].

{A box labeled Side Effects will be immediately above the cat warning box on the back panel}



DO NOT USE ON CATS
Keep cats away from treated dogs/puppies
for 24 hours. If applied to a cat or ingested
by a cat, contact your veterinarian.

{A 1.5cm x 1.5cm cat prohibition icon and warning text in a box will be located at the lower right hand corner of the back panel in yellow with black images and text.}

#### {Optional Marketing Claims}

#### **General Claims:**

5 size categories provide [smaller] weight ranges to improve [maintain][deliver] efficacy

[performance][flea and tick][control][protection] on [for] your dog/puppy

Effective on indoor and outdoor dogs/puppies

([1][3][4[[6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Spreads by dog's/puppy's movement through skin and hair oils

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Fresh][Clean][[Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

[Patent Pending]

[Can be used in households with dogs and cats]

#### **Efficacy Claims:**

Each tube [cartridge][vial] [application] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Controls fleas, ticks and mosquitoes for up to one month][Monthly treatment for control of fleas, ticks and mosquitoes]

[Aids in Control of Ticks for up to 30 days]

[Starts Killing Fleas and Ticks within 15 minutes]

[Dual Action kills adult fleas and prevents flea development]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

(Indicated) for the treatment of adult ticks, tick nymphs and tick larvae of the *Rhipicephalus sanguineus* (Brown dog tick) which (can)(may) (carry)(transmit) Rocky Mountain Spotted Fever and Canine Ehrlichiosis.

(Indicated) for the treatment and control of adult fleas, flea eggs, flea larvae, ticks, brown dog tick nymphs, brown dog tick larvae (immature ticks), and mosquitoes in dogs 10 weeks of age and older

Kills fleas, flea eggs, flea larvae, ticks, brown dog tick nymphs, brown dog tick larvae (immature ticks), and mosquitoes

Kills (Brown dog) [tick nymphs][and][kills][tick larvae][to prevent them from growing up into (biting, breeding) adults

Kills all stages of the (flea) (and) (tick) life cycle(s)

Breaks the (flea) (and) (tick) life cycle(s)

Kills all biting stages of (brown dog) ticks

Kills [brown dog tick nymphs][and][kills][brown dog tick larvae]

Kills adult (brown dog) ticks, nymphs and larvae

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (the major carrier of canine heartworm)

Monthly application for most effective protection

#### **IGR Claims:**

[Contains [InfestStop™] an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [] up to [75 days][10 weeks][2.5 months]]

[Contains [InfestStop™] [an Insect Growth Regulator (IGR) to kill flea eggs and larvae]

[Breaks Flea Life Cycle for up to [75 days][10 weeks][2.5 months]

An important step in breaking the flea life cycle

[Controls flea reinfestation for up to [75 days][10 weeks][2.5 months]

 $[With\ [InfestStop^{\intercal}][S\text{-}Methoprene]\ Insect\ Growth\ Regulator\ [IGR]\ to\ Break\ Flea\ Life\ Cycle]$ 

InfestStop/Infestop™ logo

Plus][Contains][With] PRECOR® [vIGRen®][S-Methoprene][\*InfestStop™], the first insect growth regulator for flea control

[(S)-Methoprene][\*InfestStop™] Insect Growth Regulator (IGR) interrupts the development of the flea life cycle [at the egg stage]

[(S)-Methoprene][\*InfestStop™] Insect Growth Regulator (IGR) prevents the development of flea eggs into adult fleas and [inhibits the development of flea eggs into adult fleas]

Flea control for dogs with PRECOR® [vIGRen®][\*InfestStop™] Insect Growth Regulator (IGR)

[Kills][Prevents][Keeps] flea eggs from hatching for up to [75 days][2.5 months][10 weeks]

\*(S)-Methoprene (Must occur on same panel wherever \*InfestStop™ is used)

#### **Applicator Claims**

Contemporary design

[brand name] [Applicator] helps to prevent getting liquid on [your] hands

[brand name] [Applicator] tip parts hair to help [liquid][application] get down to [the][your][dog's/puppy's] skin

Ergonomically contoured [ergonomic][shape][design] for easy handling [ease of use] [easy use]

For use with [only][brand name][disposable][liquid dispensing] tubes [pods] [vials] [cartridges]

[brand name] [applicator][has][provides][allows for][delivers] better grip

[brand name][provides] re-closable [re-sealable] packaging for [easy] storage

Closing [the][brand name][applicator] door automatically opens the [disposable][liquid dispensing] tube [pod][vial][cartridge]

[brand name] [Applicator] [will not drip after opening]

[brand name] [Applicator] Won't drip when set down as you go fetch [the] [your] dog/puppy

Includes unique [brand] applicator

Puts the liquid on your dog/puppy – not your hands

Directs the liquid onto your dog [/puppy] - not your hands

Directs the liquid onto your dog [/puppy] - away from your hands

Applies liquid to your dog's [/puppy's] skin - not yours

Convenient, easy to use ACCU-TIP [Applicator] [DISPENSER]

[Easy to use] Longer applicator tip for easy application to long-haired dogs/puppies

#### Thermoform claims

[disposable][liquid dispensing] tube [cartridge][vial][pod]

(Note tube/vial/cartridge/pod used interchangeably)

[brand name][disposable][liquid dispensing] [tube][vial][pod] tip [helps][to] spread out liquid [on your][dog/puppy]

Unique [cartridge] [tube][vial][pod] with flow control

[no drip][no mess][application][tube][cartridge][vial][pod]

#### **Promotional Package Copy**

One month [dose] free

One free month supply [dose] included

Bonus pack

Free [applicator][tube][vial[cartridge][pod][inside]

Designed not to drip when set on top of the counter, or table, or other flat surface.

For use with [brand] applicator

Applicator [device] not included

[brand] Refill Pack [brand][applicator [device] not included]

#### **Refill Claims**

For use [only] with [brand name][Applicator]
([1][3][4[[6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses Easy
to use [convenient] refills
[Can be used with] [Use with] [Brand Name] applicator
[Brand Name (e.g., Adams or Bio Spot, Smart Shield)] [Applicator] [Refills][Refill Pack] [Refill Pack] [for][Brand Name] Applicator
[tube][cartridge][vial][pod] refill pack [refills]
Refills [Refill Pack] available
[refill][tube][cartridge][vial][pod]design

#### Applicator name options (applicator device is used in text)

Applicator
Tool Device
Applicator Device Application
Tool

#### Thermoform name options (tube, cartridge and vial are used in the text)

Ampoule Cartridge Packet Pod Refill Tube Vial