

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FRONTLINE SPOT ON DOG 10% w/v Spot On Solution

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Fipronil.....	10% w/v
Butylhydroxyanisole E320.....	0.02% w/v
Butylhydroxytoluene E321.....	0.01% w/v
Non-aqueous vehicle...qs.....	to 100%

For full list of excipients, see section 6.1

**3. PHARMACEUTICAL FORM**

Spot-on solution.

**4. CLINICAL PARTICULARS**

**4.1 Target species**

Dogs.

**4.2 Indications for use, specifying the target species**

The treatment and prevention of infestations by fleas and ticks and as part of a treatment strategy for Flea Allergy Dermatitis, where this has been previously diagnosed by a veterinary surgeon. The product controls infestations with *Trichodectes canis* biting lice on dogs.

**4.3 Contra-indications**

In the absence of available data, the product should not be used on puppies less than 8 weeks old (and /or weighing less than 2kg) [*for the Small Dog and single pipette presentation only.*] Do not use on sick (systemic diseases, fever...) or convalescent animals.

Do not use in rabbits, as adverse reactions and even death could occur.

This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

**4.4 Special warnings for each target species**

Avoid contact with the animal's eyes.

When treating infestations of lice, all in-contact dogs should be treated with an appropriate product at the same time.

FRONTLINE SPOT ON DOG does not prevent ticks from attaching to the animals, but ticks will be killed in the first 24-48 hours after attachment, prior to full engorgement and therefore minimising the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may easily be removed by a gentle pull.

Bathing or shampooing the animal up to one hour prior to treatment does not affect the efficacy of the product.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other dogs in the household are recommended.

#### **4.5 Special precautions for use**

##### **(i) Special precautions for use in animals**

For external use only.

Animals should be weighed accurately prior to treatment.

It is important to make sure that the product is applied to an area where the animal cannot lick it off, and to make sure that animals do not lick each other following treatment.

Bathing/immersion in water within 2 days after application of the product and more frequent bathing than once a week should be avoided, as no study has been performed to investigate how this affects the efficacy of the product. Emollient shampoos can be used prior to treatment, but reduce the duration of protection against fleas to approximately 5 weeks when used weekly after application of the product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study. Dogs should not be allowed to swim in watercourses for 2 days after application (See section 6.6).

There may be an attachment of single ticks. For this reason transmission of infectious diseases cannot be completely excluded if conditions are unfavourable. Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

##### **(ii) Special precautions to be taken by the person administering the veterinary medicinal product to the animals**

This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided.

Animals or operators with a known hypersensitivity to insecticides or alcohol should avoid contact with FRONTLINE SPOT ON DOG. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

After accidental ocular exposure the eye should be rinsed carefully with plain water.

Wash hands after use. Do not smoke, drink or eat during application.

Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals should not be allowed to sleep with owners, especially children.

### **(iii) Other precautions**

The alcohol carrier may have adverse effects on painted, varnished or other household surfaces or furnishings.

## **4.6 Adverse reactions (frequency and seriousness)**

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

Among the extremely rare suspected adverse reactions, transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use.

Do not overdose.

## **4.7 Use during pregnancy, lactation or lay**

Laboratory studies using fipronil have not revealed any teratogenic or embryotoxic effect.

The safety of the product was demonstrated in breeding, pregnant and lactating bitches treated with multiple consecutive doses at up to 3 times the maximum recommended dose. The product can be used during pregnancy and lactation.

## **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.9 Amounts to be administered and administration route**

Route of administration – By topical application to the skin.

Dosage –

\*1 pipette of 0.67 ml per dog weighing over 2kg and up to 10kg  
bodyweight

\*1 pipette of 1.34 ml per dog weighing over 10kg and up to 20kg  
bodyweight

\*1 pipette of 2.68 ml per dog weighing over 20kg and up to 40kg  
bodyweight

\*1 pipette of 4.02 ml per dog weighing over 40kg and up to 60 kg  
Bodyweight

For dogs over 60kg use two pipettes of 2.68ml

Method of administration – Hold upright. Tap the narrow part of the  
pipette to ensure the contents are within the main body of the pipette.

Break back the snap-off top from the spot-on pipette along the scored line. Part  
the coat between the shoulder blades until the skin is visible. Place the tip of the  
pipette on the skin and squeeze gently at one or two spots to empty its contents  
onto the skin.

Care should be taken to avoid excessive wetting of the hair with the product since  
this will cause a sticky appearance of hairs at the treatment spot. However,  
should this occur, it will disappear within 24 hours post application.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

No adverse effects were observed in target animal safety studies in 8 week-old  
puppies, growing dogs and dogs weighing about 2 kg treated once at five times  
the recommended dose. The risk of experiencing adverse effects (see section  
4.6) may however increase when overdosing, so animals should always be  
treated with the correct pipette size according to bodyweight.

#### **4.11 Withdrawal periods**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

Fipronil is an insecticide/acaricide in the phenylpyrazole family. It acts by  
inhibiting the GABA complex, binding to the chloride channel and thereby  
blocking pre- and post-synaptic transfer of chloride ions across the membrane.  
This results in uncontrolled activity of the central nervous system and death in  
insects and acarids.

**ATC Vet Code:**

QP53AX15

## 5.1 Pharmacodynamic properties

Fipronil exhibits an insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp), ticks (*Rhipicephalus* spp, *Dermacentor* spp, *Ixodes* spp including *Ixodes ricinus*, important as the vector of Lyme disease) and lice (*Trichodectes canis*) in the dog.

FRONTLINE SPOT ON DOG is effective against flea infestation for approximately 2 months and against tick infestations for up to 1 month, depending on the level of challenge. Newly arriving fleas are killed within 24 hours of landing on the animal.

## 5.2 Pharmacokinetic properties

### \*Absorption

After topical application of the product in the dog, absorption of fipronil through the skin is slight (approx. 15%). Low levels of fipronil may be detected in the plasma, with a very high variability between dogs.

### \*Distribution

After topical application, the product will spread from the site of treatment to cover the entire surface of the animal within 24 hours. A concentration gradient of fipronil is set up on the fur of the animal extending from the point of application to the peripheral areas (lumbar zones, flanks, ...).

### \*Biotransformation

Fipronil is mainly metabolised to its sulfone derivative (RM1602), which also possesses insecticidal and acaricidal properties.

### \*Elimination

The concentrations of fipronil on the hair decrease with time to attain a level of approximately 3 to 4  $\mu\text{g.g}^{-1}$  56 days after treatment.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Polyvidone K17  
Polysorbate 80  
Ethanol  
Ethyl Digol

## **6.2 Major incompatibilities**

None known incompatibility.

## **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

## **6.4 Special precautions for storage**

Store in the original package.

Store in a dry place.

Do not store above 30°C.

Flammable.

## **6.5 Nature and composition of immediate packaging**

Heatformed shell containing an extractable volume of 0.67ml, 1.34ml, 2.68ml or 4.02ml: double foiled film composed of polypropylene coloured on its external surface with blue Pantone 293C and a copolymer of polyacrylonitrile-methacrylate in contact with the solution (200µm/350µm).

Opercule: triple foiled film composed of polyethylene terephthalate opacified with titanium dioxide, aluminium and copolymer of polyacrylonitrile-methacrylate in contact with the solution (12µm /12µm/35µm).

Frontline Spot On Dog is available in the following presentations:

- Blister card containing 1 pipette of 0.67ml of the solution.
- Foil blister strips containing 3 pipettes of 0.67ml of the solution. The foil blister strips are packed into cartons containing 3 or 6 pipettes.
- Blister card containing 1 pipette of 1.34ml of the solution.
- Foil blister strips containing 3 pipettes of 1.34ml of the solution. The foil blister strips are packed into cartons containing 3 or 6 pipettes.
- Blister card containing 1 pipette of 2.68ml of the solution.
- Foil blister strips containing 3 pipettes of 2.68ml of the solution. The foil blister strips are packed into cartons containing 3 or 6 pipettes.
- Blister card containing 1 pipette of 4.02ml of the solution.
- Foil blister strips containing 3 pipettes of 4.02ml of the solution. The foil blister strips are packed into cartons containing 3 or 6 pipettes.

## **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

**7. MARKETING AUTHORISATION HOLDER**

Merial Animal Health Limited  
PO Box 327  
Sandringham House  
Sandringham Avenue  
Harlow Business Park  
Harlow, Essex, CM19 5TG  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER(S)**

Vm 08327/4132

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

27 November 2006

**10. DATE OF REVISION OF THE TEXT**

March 2010

**11. ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE**

Not applicable.