

SUMMARY OF PRODUCT CHARACTERISTICS

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. The product controls infestations with *Trichodectes canis* biting lice on dogs.

4.3 Contra-indications

Do not use on puppies less than 8 weeks old (and /or weighing less than 2kg) Do not use on animals that are unwell, are undergoing treatment for, or are recovering from illness.

Do not use in animals with known hypersensitivity to the active substance or to any of the other ingredients.

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

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

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.

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, before they are fully fed 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 effectiveness of the product.

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.

Skin softening 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.

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.

Avoid contact with the animal's eyes.

Do not overdose.

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

Keep stored pipettes in the original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately

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

People 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.

Dogs should not be allowed to swim in watercourses for 2 days after application (See section 6.6).

4.6 Adverse reactions (frequency and seriousness)

If licking occurs, a brief period of excessive salivation/drooling may be observed due mainly to the solvents in the product.

Among the extremely rare suspected adverse reactions, short-lived skin reactions at the application site (skin discoloration, local hair loss, itchiness, reddening) and general itchiness or hair loss, have been reported after use. Exceptionally, excessive drooling, reversible nervous signs including hyperaesthesia (increased sensitivity to light and sound or overexcited or unusual behavior), depression, vomiting or respiratory signs have been observed after use.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Laboratory studies using fipronil have not revealed any evidence of toxicity to the embryo or developmental abnormalities in the young.

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 according to bodyweight, as follows:

*1 pipette of 0.67 ml per dog weighing 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 against the skin and squeeze gently at one or two spots to empty its contents directly onto the skin, preferably at two spots, one at the base of the skull and a second 2-3cms further back. .

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

Pharmacotherapeutic group: Other ectoparasiticides for topical use.

ATC Vet Code: QP53AX15

5.1 Pharmacodynamic 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.

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 kills fleas and ticks.

*Elimination

The concentrations of fipronil on the hair decrease with time to attain a level of approximately 3 to 4 µg.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
Harlow Business Park
Harlow
Essex
CM19 5TG

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

November 2015

11. ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE

Not applicable.

Approved: 20 November 2015

