

## Presentation

Spot on solution containing 10% w/v fipronil. Presented in plastic pipettes, each containing 0.67 ml (67 mg fipronil), 1.34 ml (134 mg fipronil), 2.68 ml (268 mg fipronil) or 4.02ml (402 mg fipronil).

## Uses

The treatment and prevention of infestations by fleas (*Ctenocephalides* spp.) and ticks (*Rhipicephalus* spp., *Dermacentor* spp. and *Ixodes* spp.) 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. FRONTLINE Spot On Dog can be used in puppies from 8 weeks of age and weighing over 2kg.

## Dosage and administration

### *Route of administration*

By topical application to the skin.

### *Dosage*

1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight (approximately 7.5 - 15 mg/kg).

1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight (7.5 - 15 mg/kg).

1 pipette of 2.68 ml per dog weighing over 20 kg and up to 40 kg bodyweight (7.5 - 15 mg/kg).

1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight (7.5 - 15 mg/kg).

For dogs over 60 kg bodyweight, use two pipettes of 2.68 ml.

### *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 of 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.

## Contra-indications, warnings, etc

For animal treatment only.

For external use only.

Animals should be weighed accurately prior to treatment.

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

Flammable.

Animals or operators with a known hypersensitivity to insecticides or alcohol should avoid contact with FRONTLINE Spot On Dog.

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.

Do not use on sick (systemic diseases, fever....) or convalescent animals.

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

Do not overdose.

It is important to apply the dose to an area where the animal cannot lick it off, and to make sure that animals do not lick each other following treatment. If licking occurs, a brief period of hypersalivation may occur, due mainly to the nature of the carrier.

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

Dogs should not be allowed to swim in watercourses for 2 days after application.

#### *Operator warnings*

The product can cause mucous membrane and eye irritation and so contact with the mouth and eyes should be avoided.

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.

Avoid contact with the animal's eyes.

Wash hands after use.

Do not smoke, eat or drink 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.

Ensure that treated animals do not groom each other after treatment until dry.

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers. Dispose of used packaging in the household refuse.

Unused product should be returned to the veterinary surgeon.

### **Pharmaceutical precautions**

Store in the original package.

Store in a dry place.

Do not store above 30°C.

Keep out of reach of children.

### **Legal category**

NFA-VPS (previously POM-V)

Flammable.

### **Packaging Quantities**

Blister packs each containing 1 pipette of 0.67ml, or 3 or 6 pipettes of either 0.67 ml, 1.34 ml, 2.68 ml or 4.02 ml.

### **Further information**

Fipronil is a member of the phenylpyrazole family of non-systemic insecticides/acaricides, which acts by blocking the GABA receptor to kill the target parasite on contact.

FRONTLINE Spot On Dog is effective against flea infestation for approximately two months and against tick infestation for up to one month, depending on the level of environmental challenge. Newly arriving fleas are killed within 24 hours of landing on the animal. Re-treatment may safely be carried out at one month intervals.

FRONTLINE Spot On Dog is licensed for use as part of a strategy for the treatment of Flea Allergy Dermatitis. For this condition, monthly application to the allergic patient and to other dogs in the household is recommended.

FRONTLINE Spot On Dog does not prevent all ticks attaching to the animal, 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 disease. Once dead, ticks will often drop off the animal, but any remaining ticks may easily be removed by a gentle pull, preferably using tweezers. 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.

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

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

safety of the product was demonstrated in breeding, pregnant and lactating bitches treated with multiple consecutive doses with up to 3 times the maximum recommended dose. FRONTLINE Spot On Dog can be used in breeding, pregnant and lactating bitches.

No adverse effects were seen in 8-week old puppies, growing dogs and dogs weighing about 2 kg treated once at five times the recommended dose. The risk of adverse effects may increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight. Safety data are not available for use of the product in animals less than 8 weeks of age.

After the topical application of FRONTLINE Spot On Dog, the product will spread from the site of treatment to cover the entire surface of the animal within 24 hours. After application, absorption of fipronil through the skin is slight.

No known incompatibilities exist for the use of other insecticides or flea control products concurrently with FRONTLINE Spot On Dog.

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

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