

Frontline Combo Spot-On Dog

Introduction



Company name:
Address:

[Merial Animal Health Ltd](#)

**PO Box 327
Sandringham House
Harlow Business Park
Harlow
Essex CM19 5TG**

Telephone:

01279 775858

Fax:

01279 775888

Email:

ukenquiry@merial.com

Website:

www.merial.com

Presentation

Spot-on solution.

Small: 1 pipette of 0.67 ml contains fipronil 67 mg, (S)-methoprene 60.30 mg.

Medium: 1 pipette of 1.34 ml contains fipronil 134 mg, (S)-methoprene 120.60 mg.

Large: 1 pipette of 2.68 ml contains fipronil 268 mg, (S)-methoprene 241.20 mg.

XL: 1 pipette of 4.02 ml contains fipronil 402 mg, (S)-methoprene 361.80 mg.

Uses

To be used against infestations with fleas, ticks and/or biting lice.

- Elimination of fleas (*Ctenocephalides* spp.) and insecticidal efficacy against new infestations with adult fleas persists for 8 weeks.

- Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity) and larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for 8 weeks after application.

- Elimination of ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*). The product has persistent acaricidal efficacy for up to 4 weeks against ticks.

- Elimination of biting lice (*Trichodectes canis*).

The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Dosage and administration

Dosage

1 pipette of 0.67 ml (S) per dog weighing over 2 and up to 10 kg;

1 pipette of 1.34 ml (M) per dog weighing over 10 kg and up to 20 kg;

1 pipette of 2.68 ml (L) per dog weighing over 20 kg and up to 40 kg;

1 pipette of 4.02 ml (XL) per dog weighing over 40 kg;

corresponding to a minimum recommended dose of 6.7 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, by topical application to the skin.

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

Method of administration

Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip. Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.

Contra-indications, warnings, etc

For animal treatment only.

In the absence of available data, the product should not be used on puppies less than 8 weeks old and/or weighing less than 2 kg. 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 may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

The product can be used during pregnancy and lactation.

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.

Do not overdose.

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

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.

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.

There are no known interactions with other medications.

Among the extremely rare suspected adverse reactions, transient cutaneous reactions at the application site (skin discolouration, 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.

Avoid contact with the animal's eyes.

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

Operator safety:

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

This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided. After accidental ocular exposure the eye should be rinsed carefully with plain water.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

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 are not allowed to sleep with owners, especially children.

Wash hands after use.

Do not smoke, drink or eat during application.

Pharmaceutical precautions

Keep out of reach of children.

Do not store above 30°C. Store in the original package.

Any unused product or waste material should be disposed of in accordance with guidance from the local waste regulation authority.

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

Legal category

POM-V

Packaging Quantities

Blister card of 1 × 0.67 ml (S) pipette with a scored tip.

Box of 1 or 2 blister card(s) of 3 × 0.67 ml (S), 1.34 ml (M), 2.68 ml (L), 4.02 ml (XL) pipettes with a scored tip.

Further information

The product is an insecticidal and acaricidal solution for topical use, containing an association of an adulticidal active ingredient, fipronil, in combination with an ovicidal and larvicidal active ingredient, (S)-methoprene.

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by interacting with ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarines. Fipronil kills fleas within 24 hours and ticks (*Dermacentor variabilis*, *Rhipicephalus sanguineus*, *Ixodes scapularis*, *Ixodes ricinus*, *Haemaphysalis longicornis*, *Haemaphysalis flava*, *Haemaphysalis campanulata*) and lice within 48 hours post-exposure.

(S)-Methoprene is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues that inhibit the development of immature stages of insects. This compound mimics the action of juvenile hormone and causes impaired development and death of the developing stages of fleas. The on-animal ovicidal activity of (S)-methoprene results from either direct penetration of the eggshell of newly laid eggs or from absorption through the cuticle of the adult fleas. (S)-methoprene is also effective in preventing flea larvae and pupae from developing, which prevents contamination of the environment of treated animals with the immature stages of fleas.

Both (S)-methoprene and fipronil are well-distributed in the haircoat of a dog within one day after application. The concentrations of fipronil and (S)-methoprene in the haircoat decrease with time and are detectable for at least 60 days after dosing. Parasites are killed through contact rather than systemic exposure.

No pharmacological interaction between fipronil and (S)-methoprene was noted.

Marketing authorisation number

Vm 08327/4211-4.