



FRONTLINE SPOT-ON DOG 10% w/v SPOT-ON SOLUTION

Qualitative and quantitative composition

Each pipette contains:

Fipronil 10% w/v

Butylhydroxyanisole (E320) 0.02% w/v

Butylhydroxytoluene (E321) 0.01% w/v

Non-aqueous vehicle qs to 100%

For the full list of excipients, see below.

Pharmaceutical form Spot-on solution.

Clinical particulars *Target species:* Dogs.

Indications for use: The treatment and prevention of infestations by fleas and ticks. The product controls infestations with *Trichodectes canis* biting lice on dogs.

Contra-indications: Do not use on puppies less than 8 weeks old (and/or weighing less than 2 kg). 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.

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.

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.

Special precautions to be taken by the person administering the product to 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.

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 Disposal Section.

Adverse reactions: 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 behaviour), 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).

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.

Interactions: None known.

Amounts to be administered and administration route:

Route of administration: By topical application to the skin according to bodyweight, as follows:

Weight (kg)	Dosage
2–10	1 x 0.67 ml pipette
> 10–20	1 x 1.34 ml pipette
> 20–40	1 x 2.68 ml pipette
> 40–60	1 x 4.02 ml pipette
> 60	2 x 2.68 ml pipettes

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

Overdose: 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.

Pharmacological particulars

ATCvet code: QP53AX15

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.

Pharmaceutical particulars

Excipients: Polyvidone K17, Polysorbate 80, Ethanol, Ethyl digol.

Major incompatibilities: No known incompatibility.

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

Special precautions for storage: Store in the original package. Store in a dry place. Do not store above 30°C. Flammable.

Immediate packaging: Blister cards containing 1, 3 or 6 pipettes of either 0.67 ml, 1.34 ml, 2.68 ml or 4.02 ml.

Disposal: 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.

Marketing Authorisation Number Vm 08327/4132

Marketing Authorisation Holder Merial Animal Health Ltd, Ellesfield Avenue, Bracknell, RG12 8YS

Manufacturer Merial, 4 chemin du Calquet, 31000 Toulouse (France)

Legal category AVM-GSL

GTIN (Global Trade Item No.)

Frontline Spot-On Dog 0.67 ml x 1 03661103045212
Frontline Spot-On Dog 0.67 ml x 3 03661103003441
Frontline Spot-On Dog 0.67 ml x 6 03661103003755
Frontline Spot-On Dog 1.34 ml x 1 03661103045229
Frontline Spot-On Dog 1.34 ml x 3 03661103003434
Frontline Spot-On Dog 1.34 ml x 6 03661103003748
Frontline Spot-On Dog 2.68 ml x 1 03661103045236
Frontline Spot-On Dog 2.68 ml x 3 03661103003427
Frontline Spot-On Dog 2.68 ml x 6 03661103003731
Frontline Spot-On Dog 4.02 ml x 1 03661103045243
Frontline Spot-On Dog 4.02 ml x 3 03661103004615
Frontline Spot-On Dog 4.02 ml x 6 03661103004608

For further information, contact ukcompanionanimal@merial.com

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For animal treatment only. Keep out of the sight and reach of children.