Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Spot On Dog

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette contains:

Active Substance	
Fipronil	10 % w/v
Excipients	
Butylhydroxyanisole (E320)	0.02 % w/v
Butylhydroxytoluene (E321)	0.01 % w/v
Non-aqueous vehicle q.s. to	100 % w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Spot-on solution.
Clear to light brownish-yellow 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 in dogs. Frontline Spot On Dog has been shown to significantly reduce the incidence of Flea Allergy Dermatitis. Ticks will usually detach from the treated host within 24 to 48 hours after infestation, without having had a blood meal.

Frontline Spot On Dog rapidly controls infestations with *Trichodectes canis* (biting lice) on dogs.

4.3 Contraindications

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.
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.

4.5 Special precautions for use

Special precaution(s) for use in animals

For external use only.
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.

From 48 hours after treatment, the duration and efficacy of Frontline Spot On Dog is not affected by bathing or water immersion. 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).

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. 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.

For optimum control of flea and tick problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.
Special precautions to be taken by the person administering the veterinary medicinal product to animals

This product can cause mucous membrane and eye irritation. Therefore, contact of the product with the 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 exposure, the eye should be rinsed carefully with plain water. As with all insecticides
- 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.
Flammable.

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, pruritis, erythema) and general pruritis 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: external use, by application to the skin.

Posology:
1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight.
1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight.
1 pipette of 2.68 ml per dog weighing over 20 kg and up to 40 kg bodyweight.
1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight.

Method of administration:
Break 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 on to 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.

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 with overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use
ATCvet 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 insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp), lice (*Trichodectes canis*) and ticks (*Rhipicephalus* spp*, Dermacentor* spp*, Ixodes* spp) in the dog.

Fipronil is active against several tick species, including *Ixodes ricinus*, important as the vector of Lyme disease.

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 particulars

*Absorption

After a local application of FRONTLINE SPOT ON DOG in the dog, fipronil is slightly absorbed (approx. 15%) through the skin. Low levels of fipronil may be detected in the plasma, with a very high variability between dogs.

*Distribution

After application of FRONTLINE SPOT ON DOG, 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 highly metabolised to its sulfone derivative (RM1602), which also possesses insecticidal and acaridical properties.

*Elimination

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
Butylhydroxytoluene (E321)
Povidone K17
Polysorbate 80

Ethanol
Diethylene glycol monoethyl ether

6.2 Major incompatibilities

None known.

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 original package. Store in a dry place.

6.5 Nature and composition of immediate packaging

Heatformed shell containing an extractable volume of 0.67 ml, 1.34 ml, 2.68 ml, or 4.02 ml: double foiled film composed of polypropylene and a copolymer of polyacrylonitrile-metacrylate in contact with the solution (200 µm/350 µm).

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

Presented in packs containing 1 or 3 pipettes, and cartons containing 3, 6, 9 or 12 units.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused product or waste material should be disposed of in accordance with national requirements. Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/049/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th June 1998
Date of last renewal: 11th June 2008

10 DATE OF REVISION OF THE TEXT

May 2018