

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Spot On Cat

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette contains:

Active Substance

Fipronil	10	% w/v
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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

Cats.

4.2 Indications for use, specifying the target species

The treatment and prevention of infestations by fleas and ticks in cats. Treatment with Frontline Spot On Cat has been shown to result in a significant reduction in the incidence of Flea Allergy Dermatitis in cats. Ticks will usually detach from the treated host within 24 to 48 hours after infestation, without having had a blood meal.

Frontline Spot-On Cat is effective for up to 5 weeks in cats, depending on the level of environmental challenge. Newly arriving fleas are killed within 24 hours of landing on the animal.

FRONTLINE Spot On Cat rapidly controls re-infestation for up to 4 weeks with all stages of (*Ixodes* spp.) ticks depending on the level of environmental challenge.

FRONTLINE Spot On Cat rapidly controls infestations with *Felicola subrostratus* (biting lice) on cats.

4.3 Contraindications

In the absence of available data, the product should not be used on kittens less than 8 weeks old and/or weighing less than 1 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.

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.

No data on the effect of bathing/shampooing on the efficacy of the product in cats are available. However, based on the information available for dogs shampooed from two days after application of the product, it is not recommended to bath animals within 2 days after application of the product. 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.

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 Cat. 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 (scaling, 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 have been observed after use.

Do not overdose.

4.7 Use during pregnancy, lactation or lay

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

The safety of the product was demonstrated in breeding, pregnant and lactating queens treated with multiple consecutive doses with 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 local application to the skin.

Dosage: 1 pipette of 0.5 ml per cat (Approximately 7.5 - 15 mg/kg)

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 to empty its contents on to the skin, preferably at two spots, one at the base of the skull and a second 2-3 cms 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 undesirable effects were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months. The risk of experiencing adverse effects may however increase with overdosing (see section 4.6). Itching may occur following treatment. Overdose application of the product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

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 a new 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 (*Felicola* spp.) and ticks (*Ixodes* spp., *Rhipicephalus* spp. and *Dermacentor* spp.) in the cat.

FRONTLINE SPOT ON CAT is effective for up to 5 weeks and against tick infestations (*Ixodes* spp.) for up to 4 weeks in cats, depending on the level of environmental challenge. Newly arriving fleas are killed within 24 hours of landing on the animal.

5.2 Pharmacokinetic particulars

*** Absorption**

After a topical application of the Spot On in the cat, there is very little passage of fipronil through the skin.

*** Distribution**

After application, 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**

In 'in vitro' studies with subcellular liver fractions, the principal metabolite is the sulfone derivative of fipronil. However, this may be of limited relevance 'in vivo' as fipronil is poorly absorbed in the cat.

*** Elimination**

The concentrations of fipronil on the hair decrease with time to attain a level of approximately $1 \mu\text{g.g}^{-1}$ two months 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 0.5ml: double foiled film composed of polypropylene and a copolymer of polyacrylonitrile-methacrylate in contact with the solution (200 µm /350 µm).

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

Presented in blister cards containing 1 or 3 pipettes, and cartons containing 3, 6, 9 or 12 pipettes.

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)

VPA10454/048/001

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