

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE SPOT ON CAT 10% w/v Spot On Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 0.5 ml contains:

Active substance:

Fipronil 50.00 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylhydroxyanisole (E320)	0.10 mg
Butylhydroxytoluene (E321)	0.05 mg
Ethanol	
Polysorbate 80 (E433)	
Polyvidone K17	
Diethylene glycol monoethyl ether	

Clear amber spot-on solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats

3.2 Indications for use for each target species

The treatment and prevention of flea and tick infestations and/or biting lice.

- Treatment of flea infestations (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 5 weeks.
- Treatment of tick infestations (*Ixodes* spp., *Dermacentor* spp., *Rhipicephalus* spp.). The veterinary medicinal product has a persistent acaricidal efficacy for up to 1 month against ticks (based on experimental data).
- Treatment of infestations with biting lice (*Felicola subrostratus*).

3.3 Contraindications

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

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

Do not use on rabbits, as adverse events and even death could occur. In absence of

studies, the use of the veterinary medicinal product is not recommended in non-target species.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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

There may be an attachment of single ticks. For this reason, transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

In case of infestation, carpets and non-washable furnishings should be treated with an appropriate insecticide household spray to kill eggs and larvae already in the home. Wash all pet bedding at 60°C as fleas often infest the animal's regular resting areas. Vacuum the whole house, including under furniture.

Other pets living in the same household should also be treated with a suitable veterinary medicinal product.

3.5 Special precautions for use

Special precautions for safe use in the target species:

For external use only.

Avoid contact with the animal's eyes.

It is important to make sure that the veterinary medicinal product is applied to an area where the animal cannot lick it off and to make sure that animals do not groom each other following treatment until the application site is dry.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Keep 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 veterinary medicinal product can cause mucous membrane, skin and eye irritation. Therefore, contact of the veterinary medicinal product with mouth, skin and eyes should be avoided.

In the event of accidental exposure to the eye, it should be rinsed carefully with water.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with a known hypersensitivity (allergy) to insecticides, such as fipronil, or to alcohol should avoid contact with the veterinary medicinal product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

Wash hands after use.

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.

Do not smoke, drink or eat during application.

Special precautions for the protection of the environment:

See section 5.5.

Other Precautions:

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

3.6 Adverse events

Cats:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Application site reactions (skin scaling ¹ , localised hair loss ¹ , itching ¹ , reddening ¹). Generalised itching or hair loss. Hypersalivation ² , vomiting. Hyperaesthesia ^{3,4} . Excitation ³ , unusual behaviour ³ . Depression.
--	--

¹ Transient

² If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the solvents in the veterinary medicinal product.

³ Reversible

⁴ Increased sensitivity to light and sound

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The veterinary medicinal product can be used during pregnancy and lactation. Laboratory studies using fipronil have not shown any evidence of toxicity to the embryo or

developmental abnormalities in the young.

The safety of the veterinary medicinal product was demonstrated in breeding, pregnant and lactating queens treated with multiple consecutive doses with up to 3 times the maximum recommended dose.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with other flea products which are applied directly on to the animal.

3.9 Administration routes and dosage

Spot-on.

Cats should be weighed accurately prior to treatment.

One pipette of 0.5 ml per cat, corresponding to a minimum recommended dose of 5 mg/kg of fipronil, by topical application to the skin.

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

For infestations with fleas and/or ticks, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

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 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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Do not overdose.

The risk of experiencing adverse effects may however increase with overdosing (see section 3.6.).

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.

Itching may occur following treatment.

Overdose application of the veterinary medicinal product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AX15

The veterinary medicinal product is an insecticidal and acaricidal solution for topical use, containing an adulticidal active ingredient, fipronil.

4.2 Pharmacodynamics

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 and acarids. Fipronil kills fleas within 24 hours, ticks (*Dermacentor* spp., *Rhipicephalus* spp., *Ixodes* spp.) and lice within 48 hours post-exposure.

4.3 Pharmacokinetics

Absorption

After local application of the veterinary medicinal product on the cat, absorption of fipronil through the skin is negligible.

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 µg.g⁻¹ two months after treatment.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25°C.

Store in the original packaging.

Store in a dry place.

Flammable.

5.4 Nature and composition of immediate packaging

A blue pipette composed of a heat-formed shell (polyacrylonitrile-methyl acrylate copolymer in contact with the solution / polypropylene) and a film (polyacrylonitrile-methyl acrylate copolymer in contact with the solution / aluminium / polyethylene terephthalate).

Or

A blue pipette composed of a heat-formed shell (polyethylene in contact with the solution / ethylene vinyl alcohol / polyethylene / polypropylene / cyclic-olefin-copolymer / polypropylene) and a film (polyethylene in contact with the solution / ethylene vinyl alcohol / polyethylene / aluminium / polyethylene terephthalate).

Package sizes:

Blister card of 1 x 0.5ml pipette with a scored tip

Box of 1 foil blister strip of 1 x 0.5 ml pipette with a scored tip

Box of 1 foil blister strip of 1 x 0.5 ml pipette with a scored tip and two empty blister spaces

Box of 1 foil blister strip of 3 x 0.5 ml pipettes with a scored tip

Box of 2 foil blister strips of 3 x 0.5 ml pipettes with a scored tip

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty containers.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 08327/5077

8. DATE OF FIRST AUTHORISATION

27 November 1996

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 12 August 2026