SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTLINE PLUS SPOT-ON CAT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 0.5 ml contains:

Active substances:
Fipronil 50.00 mg
(S)-methoprene 60.00 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)	
Povidone	
Diethylene glycol monoethyl ether	

Clear amber spot-on solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats and ferrets

3.2 Indications for use for each target species

Cats:
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 4 weeks. Prevention of the multiplication of fleas for 6 weeks after application by killing flea eggs (ovicidal activity) and larvae (larvicidal activity). By killing the larvae, pupae are prevented from developing.
- Treatment of tick infestations (*Ixodes ricinus, Dermacentor variabilis, Rhipicephalus sanguineus*). The veterinary medicinal product has a persistent acaricidal efficacy for up to 2 weeks against ticks (based on experimental data).
- Treatment of infestations with biting lice (*Felicola subrostratus*).

Ferrets:
The treatment and prevention of flea and tick infestations.
- Treatment of flea infestations (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 weeks. Prevention of the multiplication of fleas after application by killing flea eggs (ovicidal activity) and larvae (larvicidal activity). By killing the larvae, pupae are prevented from developing.
- Treatment of tick infestations (*Ixodes ricinus*). The veterinary medicinal product has a persistent acaricidal efficacy for 4 weeks against ticks (based on experimental data).

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. The veterinary medicinal product should not be used on ferrets less than 6 months old.
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 substances 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 and ferrets is available. However, based on information available for dogs, 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

<u>Special precautions for safe use in the target species:</u>
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.

The potential toxicity of the veterinary medicinal product for kittens of less than 8 weeks of age in contact with a treated queen is not documented. Special care should be taken in this case.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Keep pipettes in 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 (S)-methoprene, 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 and Ferrets:

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. Increased sensitivity to stimulation[3], depression[3], other nervous signs[3].

[1] Transient
[2] If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

[3] Reversible

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

Cats
The veterinary medicinal product can be used during pregnancy in cats.
For treatment during the lactating period, see section 3.5.
Laboratory studies in cats have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

Ferrets
The safety of the veterinary medicinal product has not been established in ferrets during pregnancy and lactation. Use only according to the risk-benefit assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Spot-on application

Animals should be weighed accurately prior to treatment.

Cats:
One pipette of 0.5 ml per cat, corresponding to a minimum recommended dose of 5 mg/kg of fipronil and 6 mg/kg of (S)-methoprene, by topical application to the skin.

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

Ferrets:
One pipette of 0.5 ml per ferret, corresponding to a dose of 50 mg for fipronil and 60 mg for (S)-methoprene per ferret, by topical application to the skin.

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 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.

Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

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

Do not overdose.
The risk of experiencing adverse effects may increase with overdosing (see section 3.6).

Cats:
No undesirable events 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 5 times the recommended dose for 6 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.

Ferrets:
In ferrets aged 6 months and older and treated once every 2 weeks for 4 treatments, at 5 times the recommended dose, body weight loss was observed in some animals.

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: QP53AX65

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

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 or acarids. Fipronil kills fleas within 24 hours, 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 killing flea eggs and larvae and preventing pupae from developing, which prevents contamination of the environment of treated animals with the immature stages of fleas.

4.3 Pharmacokinetics

Studies of metabolism of fipronil have demonstrated that the major metabolite is the sulfone derivative of fipronil.
(S)-methoprene is extensively degraded into carbon dioxide and acetate that are subsequently incorporated into endogenous materials.

The pharmacokinetic profiles after topical application of fipronil and (S)-methoprene in combination were studied in cats in comparison to intravenous dosing of fipronil or (S)-methoprene alone. This established absorption and other pharmacokinetic parameters under conditions mimicking clinical practice. The topical application, with additional potential oral exposure from licking, resulted in overall systemic absorption of fipronil (18%) with a mean maximum concentration (C_{max}) of approximately 100 ng/ml fipronil and 13 ng/ml of fipronil sulfone in plasma.
Peak fipronil plasma concentrations are rapidly attained (mean t_{max} approximately 6 hours) and decline with a mean terminal half-life of approximately 25 hours.
Fipronil is slightly metabolised to fipronil sulfone in cats.

Plasma concentrations of (S)-methoprene were generally below the limit of quantitation (20 ng/ml) in cats after topical application.

Both (S)-methoprene and fipronil, together with its major metabolite, are well-distributed in the haircoat of cats within one day after application. The concentrations of fipronil, fipronil sulfone and (S)-methoprene in the hair coat decrease with time and are detectable for at least 59 days after dosing. Parasites are killed through contact rather than by systemic exposure.

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

The pharmacokinetic profile of the veterinary medicinal product has not been investigated in ferrets.

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

Nature of primary packaging

A green 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 green 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).

Sales presentations

Blister card of 1 x 0.5 ml pipette with a scored tip
Box of 1 blister card of 1 x 0.5 ml pipette with a scored tip
Box of 1 blister card of 1 x 0.5 ml pipette with a scored tip and two empty blister spaces
Box of 1 blister card of 3 x 0.5 ml pipettes with a scored tip
Box of 1 blister card of 4 x 0.5 ml pipettes with a scored tip
Box of 2 blister cards 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 and (S)-methoprene 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 Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 61700/3077

8. DATE OF FIRST AUTHORISATION

13 October 2015

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: 04 September 2026