SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Frontline Spray 0.25% w/v cutaneous spray solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Fipronil 0.25 % w/v

Excipients:

Qualitative composition of excipients and other constituents
Copovidone
Isopropyl Alcohol
Water purified

Clear, colourless to yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats.

3.2 Indications for use for each target species

The treatment and prevention of flea (*Ctenocephalides* species) and tick (*Ixodes* species) infestations in cats and dogs.
The product can be used as part of a treatment strategy for Flea Allergy Dermatitis in cats and dogs where this has been previously diagnosed by a veterinary surgeon.

The product controls infestations with *Trichodectes canis* biting lice on dogs, and *Felicola subrostratus* biting lice on cats.

3.3 Contraindications

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

Do not use in rabbits, as adverse reactions and even death could occur.

3.4 Special warnings

Do not exceed the recommended dosage.
Avoid contact with the animal's eyes.
Do not spray directly onto areas of broken skin.

Allow treated animals to dry in a well-ventilated room (see also section 3.5).
Do not confine animals in an enclosed space or pet carrier until the coat is totally dry.
In the absence of specific tolerance and efficacy data, the product is not recommended for the treatment of species other than cats and dogs.
When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Animals should be weighed accurately prior to treatment.
It is important to make sure that animals do not lick each other following treatment.
There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.
Keep treated animals away from fires or other sources of heat, and surfaces likely to be affected by the alcohol spray, for at least 30 minutes following spraying and until the fur is totally dry. Do not spray on a naked flame or any incandescent material.
For external use only

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

This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the veterinary medicinal product and the mouth and eyes should be avoided. Following accidental ocular exposure the eye(s) should be rinsed carefully with clean water.

People with a known hypersensitivity to fipronil or any of the other ingredients 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.

Treated animals should not be handled until the fur is dry, and children should not be allowed to play with treated animals until the fur 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 are not allowed to sleep with owners, especially children.

Spray animals in the open air or a well-ventilated room.
Do not breathe spray. Do not smoke, drink or eat during application.
Personal protective equipment consisting of PVC or nitrile gloves should be worn when handling the veterinary medicinal product. It is recommended to wear a waterproof apron for the protection of clothing.
If clothing becomes heavily wetted with the veterinary medicinal product, it should be removed and washed before re-use.

Dispose of gloves after use and then wash hands with soap and water.

Wash splashes from skin with soap and water immediately. If irritation occurs, seek medical advice and show the package leaflet or the label to the physician. People with

known sensitivity or asthma may be particularly sensitive to the veterinary medicinal product. Do not use veterinary medicinal product if you have previously experienced a reaction to it.

Treatment of multiple animals: Good ventilation is particularly important where several animals are to be treated. Treat multiple animals outside, or reduce the build up of vapour by removing the animals from the treatment room while the alcohol is evaporating and ensure that the treatment room is well ventilated between individual treatments. In addition, ensure that the drying room is well ventilated and avoid housing several recently treated animals within the same air space.

Special precautions for the protection of the environment:

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

3.6 Adverse events

Dogs, cats:

Very rare <1 animal / 10,000 animals treated, including isolated reports):	Hypersalivation[1], vomiting Reddening of the skin[2], itching[2], hair loss[2] Hyperaesthesia[3,4], depression[4], other nervous signs[4] Respiratory signs

[1] If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
[2] Transient
[3] Increased sensitivity to stimulation
[4] 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

Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit.

The formulation is very well tolerated by puppies following treatment of the lactating bitch. Data are not available on treatment of pregnant queens or nursing queens.

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

Route of administration: mechanical pump spray for external use.

Method of administration: Adjust the pump nozzle to spray setting.
Spray the entire body of the animal and apply from a distance of approximately 10-20cm.
Apply against the lay of the hair and make sure that the entire coat of the animal is dampened. Ruffle the coat, especially in long haired animals, so that the product penetrates down to the skin.
For treatment of the head region, and when treating young or nervous pets, application may be carried out by spraying onto a gloved hand and rubbing the product into the coat. Allow to dry naturally. Do not towel dry.

Posology: In order to dampen the coat down to the skin, depending on the length of hair, apply 3 to 6 ml per kg bodyweight, (7.5 to 15mg of active ingredient per kg bodyweight) i.e. 6 to 12 pump applications per kg bodyweight of the 100ml presentation, or 2 to 4 pump applications of the 250ml and 500ml presentations.
The 100ml pack contains approximately 8 treatments for a short haired medium sized cat (4kg). The 250ml pack contains approximately 4 treatments for a short haired medium sized dog (20kg). The 500ml pack contains approximately 8 treatments for a short haired medium sized dog (20kg).

Properties: The formulation contains a coating agent. Therefore, spraying builds up a film and makes the fur glossy.
In the absence of safety studies, the minimum treatment interval is 4 weeks.
Puppies and kittens from 2 days of age may be safely treated.
Treatment of bedding, carpets and soft furnishings with a suitable insecticide will aid reduction in environmental challenge and maximise the duration of protection against re-infestation provided by the product.

The product is not suitable for direct treatment of the environment.

For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the product. Bathing or shampooing up to four times in two months has been shown to have no significant effect on the residual efficacy of the product. Monthly treatment is recommended when more frequent shampooing is carried out.

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

The risk of experiencing adverse effects (see section 4.6) may increase when overdosing, so animals should always be treated with the correct dose according to bodyweight.

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 IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:

QP53AX15

4.2 Pharmacodynamics

Fipronil exhibits insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp), ticks (*Rhipicephalus* spp. *Ixodes* spp.) and lice (*Trichodectes* spp. and *Felicola* spp.) in the dog and cat.

Fipronil is a member of the phenylpyrazole family of broad spectrum, non-systemic, insecticides/acaricides, which acts by blocking the GABA receptor to kill the target parasite on contact. The product may aid in the control of a number of ectoparasite species in dogs and cats, including *Neotrombicula autumnalis, Sarcoptes* spp. and *Cheyletiella* spp. Treatment with the product has been shown to result in a significant reduction in the incidence of flea allergy dermatitis in both dogs and cats. When used as part of a strategy for the treatment of flea allergy dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended.

4.3 Pharmacokinetics

+ Absorption
The amount of fipronil absorbed by the skin in the dog, after application of the spray to the coat and skin is extremely slight to negligible.

+ Distribution
The persistence of fipronil on the hair is very long (on average 52.5 ± 11.5 days), given that the limit of quantification of the assay method is 0.25 µg/g.

+ Biotransformation
In all species fipronil is mainly metabolised to its sulphone derivative (RM1602), which also possesses insecticidal and acaricidal properties.

The RM1602 detected on the hair after spray application in dogs may be explained by its presence in the original raw material.

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

This veterinary medicinal product does not require any special temperature storage conditions.
Highly flammable.
Protect from direct sunlight.

5.4 Nature and composition of immediate packaging

125ml spray bottle (filled to 100ml) in high density polyethylene, fitted with a mechanical pump spray delivering 0.5ml per spray (plunger in low density polyethylene).

250ml spray bottle in high density polyethylene, fitted with a mechanical pump spray delivering 1.5ml per spray (plunger in low density polyethylene).

500ml spray bottle in high density polyethylene, fitted with a mechanical pump spray delivering 1.5ml per spray (plunger in low density polyethylene).

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 Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBERS

Vm 61700/5007
Vm 61700/3007

8. DATE OF FIRST AUTHORISATION

09 December 1994

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

August 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 23 September 2026