

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

Fipronil	0.25 % w/v
Hydro-alcoholic vehicle q.s.	100.00 % w/v

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cutaneous spray solution.
Clear, colourless to yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats

4.2 Indications for use, specifying the 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.

4.3 Contra-indications

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

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 4.5(ii)).

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.

4.5 Special precautions for use

(i) Special precautions for use in animals

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.

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

This product can cause mucous membrane and eye irritation. Therefore, contact between the 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 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.

Wear PVC or nitrile gloves during treatment of animals. It is recommended to wear a waterproof apron for the protection of clothing.

If clothing becomes heavily wetted with the 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. People with known sensitivity or asthma may be particularly sensitive to the product. Do not use 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.

(iii) Other precautions

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

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 erythema, pruritus 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 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.

4.8 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.

4.9 Amounts to be administered and administration route

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.

The product is active for up to 3 months against fleas in dogs, and up to 2 months in cats, depending on the environmental challenge. It is effective against tick infestations for up to one month in dogs and cats, depending on the level of environmental challenge.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Summary presentation of the active ingredient.

Fipronil is an insecticide and acaricide from 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.

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5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

+ 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Copolymer of vinylpyrrolidin-2-one and vinyl acetate
Isopropyl Alcohol
Water Purified

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

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

6.5 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).

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local 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 Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4113

9. DATE OF FIRST AUTHORISATION

09 December 1994

10. DATE OF REVISION OF THE TEXT

November 2018

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