

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Spray 2.5 mg/ml Cutaneous Spray, Solution for Cats and Small Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains:

Active substance:

Fipronil 2.5 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous Spray, Solution
Clear, colourless liquid

4. CLINICAL PARTICULARS

4.1 Target species

Cats and Dogs

4.2 Indications for use, specifying the target species

Treatment and prevention of flea (*Ctenocephalides* spp.) and tick (*Ixodes* spp., including *Ixodes ricinus*) infestations in cats and dogs.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

Insecticidal efficacy against new infestations with adult fleas persists for up to 2 months in cats and up to 3 months in dogs, depending on environmental challenge. The product has a persistent acaricidal efficacy for up to one month against ticks, depending on the level of environmental challenge.

4.3 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.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

Do not exceed the recommended dosage.

Avoid contact with the animal's eyes. In the case of accidental eye contact immediately and thoroughly flush the eyes with water.

Do not spray directly onto areas of broken skin.

Allow treated animals to dry in a well ventilated room (see also section 4.5).

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.

For optimum efficacy, it is not recommended to bathe or shampoo animals within the two day period prior to treatment or within the two day period following treatment.

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.

For optimal control of flea infestations in multi-pet households, all dogs and cats in the household should be treated at the same time.

Fleas from pets often infest the animal's basket, bedding and regular resting areas, such as carpets and soft furnishings. These should be treated in cases of massive infestation and upon the initiation of control measures with a suitable insecticide, and vacuumed regularly.

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

Given the volume delivered by the spray pump (0.5ml/pump) the product is very suitable for use in cats and dogs up to 5-10kg bodyweight, depending on the length of hair (see also section 4.9) but not adequate for medium and large dogs.

4.5 Special precautions for use

Special precautions for use in animals

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.

The product is highly flammable, it is important to 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

People with asthma or a known hypersensitivity to insecticides or alcohol should avoid contact with the veterinary medicinal product. This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes

should be avoided. Avoid contents coming into contact with the fingers. **Wear disposable PVC or nitrile gloves during treatment of animals. It is also recommended to wear a waterproof apron for the protection of clothing.**

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

If clothing or the animal's bedding becomes wetted with the product, it should be removed and washed before re-use.

If skin contact occurs, wash immediately with soap and water. If irritation occurs, seek medical advice.

After accidental eye exposure, the eye should be rinsed carefully with clean 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.

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.

Other precautions

Fipronil may adversely affect aquatic organisms.

Dogs should not be allowed to swim in watercourses for 2 days after application (see section 6.6)

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.

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: spray pump for external use.

For dogs and cats from 2 days old weighing a minimum of 166 g to a maximum of 10 kg.

It is essential that the weight of the animal(s) to be treated is accurately determined before use of the product.

Method of administration:

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: It is important 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.

Cats/dogs weighing	Short hair	Long hair
166 g	1 pump	2 pumps
333 g	2 pumps	4 pumps
500 g	3 pumps	6 pumps
666 g	4 pumps	8 pumps
832 g	5 pumps	10 pumps
1.0 kg	6 pumps	12 pumps
1.5 kg	9 pumps	18 pumps
2.0 kg	12 pumps	24 pumps
2.5 kg	15 pumps	30 pumps
3.0 kg	18 pumps	36 pumps
3.5 kg	21 pumps	42 pumps
4.0 kg	24 pumps	48 pumps
5.0 kg	30 pumps	60 pumps
6.0 kg	36 pumps	72 pumps
7.0 kg	42 pumps	84 pumps
8.0 kg	48 pumps	96 pumps
9.0 kg	54 pumps	108 pumps
10.0 kg	60 pumps	120 pumps

The 100ml bottle contains:

- Approximately 3 to 6 treatments for a dog weighing 5 kg, depending on hair length;
- Approximately 8 treatments for a short haired cat weighing 4 kg;
- Approximately 2 treatments for a long haired dog weighing 8 kg.

Properties : The formulation contains a coating agent. Therefore, spraying builds up a film.

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

The minimum dose for the product is one pump. Therefore, this product is only suitable for puppies and kittens from 2 days old that weigh more than 166 g. Very young puppies and kittens are unable to regulate their body temperature and use of the product will have a cooling effect. For this reason, care must be taken to keep these individuals warm after treatment whilst remembering to keep treated animals away from fires or other sources of heat as the product is highly flammable.

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.

Start an appropriate symptomatic treatment in case of overdosing.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides.
ATCvet code: QP53AX15.

5.1 Pharmacodynamic properties

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.

Fipronil exhibits insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp.), ticks (*Ixodes* spp.) and lice (*Trichodectes canis* and *Felicola subrostratus*) in dogs and cats.

5.2 Pharmacokinetic particulars

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 $0.25 \mu\text{g/g}$.

This can be explained by the fact that fipronil dissolves well in fat and concentrates in the sebaceous glands. From the sebaceous glands (depot) the amount of fipronil on the skin is constantly replenished.

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

Copovidone K28
Isopropyl Alcohol
Purified water

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 1 year.

6.4 Special precautions for storage

Highly flammable.
Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

An 100ml bottle consisting of high density polyethylene, fitted with a spray pump delivering 0.5ml per pump (dip tube consisting of 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

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

Beaphar B.V.
Drostenkamp 3
8101 BX Raalte
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 41941/5002

9. DATE OF FIRST AUTHORISATION

18 October 2017

10. DATE OF REVISION OF THE TEXT

April 2022

Approved 29 April 2022

A handwritten signature in black ink, appearing to read "Hunter.", is written below the approval date. The signature is stylized and includes a vertical line to the left of the name.