

*[Version 9.1,11/2024]*

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Spray 2.5 mg/ml cutaneous spray, solution for cats and dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Fipronil 2.5 mg

### Excipients:

Qualitative composition of excipients and other constituents
Copovidone K28
Isopropyl Alcohol
Purified water

Clear, colourless liquid.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cats and dogs

### 3.2 Indications for use for each 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 veterinary medicinal product has a persistent acaricidal efficacy for up to one month against ticks, depending on the level of environmental challenge.

### 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.

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

### 3.4 Special warnings

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 veterinary medicinal product. Monthly treatment is recommended when more frequent shampooing is carried out.

The possibility that other animals in the same household can be a source of re-infection with fleas, ticks and biting lice should be considered, and these should be treated as necessary with an appropriate product.

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.

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 veterinary medicinal product is not suitable for direct treatment of the environment.

Given the volume delivered by the spray pump (0.5ml/pump) the veterinary medicinal product is very suitable for use in cats and dogs up to 5-10 kg bodyweight, depending on the length of hair (see also section 3.9) but not adequate for medium and large dogs.

### **3.5 Special precautions for use**

#### Special precautions for safe use in the target species:

For cutaneous use only.

It is important to make sure that animals do not lick each other following treatment.

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

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 veterinary medicinal product is not recommended for the treatment of species other than cats and dogs.

Puppies and kittens from 2 days of age may be safely treated.

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.

#### 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 of the veterinary medicinal product with mouth and eyes should be avoided.

People with asthma or a known hypersensitivity to insecticides or 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. If irritation occurs, seek medical advice.

After accidental ocular exposure the eye should be rinsed carefully with plain 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.

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:

Dogs should not be allowed to swim in watercourses for 2 days after application.

### **3.6 Adverse events**

Cats and dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Skin reaction <sup>1</sup> (Reddening of the skin <sup>1</sup> , Pruritus <sup>1</sup> , Alopecia <sup>1</sup> ) Hypersalivation <sup>2</sup> ; Vomiting Hyperaesthesia <sup>3</sup> , Central nervous system depression <sup>3</sup> , Neurological signs <sup>3</sup> Respiratory signs
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<sup>1</sup> Transient.

<sup>2</sup> If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

<sup>3</sup> 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**

#### Pregnancy and lactation:

Laboratory studies in the rat and rabbit have not produced evidence of any teratogenic effects. 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**

Cutaneous use.

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 15 mg of active ingredient per kg bodyweight) i.e. 6 to 12 pump applications per kg bodyweight of the 100 ml presentation.

The 100 ml 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.

Do not exceed the recommended dosage.

#### Method of administration:

Spray the entire body of the animal and apply from a distance of approximately 10-20 cm.

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 veterinary medicinal 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 veterinary medicinal product into the coat. Allow to dry naturally. Do not towel dry.

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.

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

The risk of experiencing adverse effects (see section 3.6) 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.

### **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

### **4.2 Pharmacodynamics**

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.

### **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  $52.5 \pm 11.5$  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.

### **Environmental properties**

Fipronil may adversely affect aquatic organisms.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

### **5.2 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.

### **5.3 Special precautions for storage**

Do not store above  $25^\circ\text{C}$

Highly flammable.

### **5.4 Nature and composition of immediate packaging**

A 100 ml bottle consisting of high density polyethylene (HDPE), fitted with a spray pump delivering 0.5 ml per pump (dip tube consisting of low density polyethylene (LDPE)).

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and other aquatic organisms.

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**

Beaphar B.V.

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

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

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE**

**HDPE BOTTLE 100 ml**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fiprotec Spray 2.5 mg/ml cutaneous spray, solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Fipronil 2.5 mg/ml

**3. PACKAGE SIZE**

100 ml

**4. TARGET SPECIES**

Cats and dogs

**5. INDICATIONS**

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 veterinary medicinal product has a persistent acaricidal efficacy for up to one month against ticks, depending on the level of environmental challenge.

**6. ROUTES OF ADMINISTRATION**

Cutaneous use

Apply 3 to 6 ml per kg body weight:

Short haired cats / dogs	3 ml (6 pumps) per kg body weight
Long haired cats / dogs	6 ml (12 pumps) per kg body weight
1 pump = 0.5 ml	

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 1 year.

Once opened use by ...

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C.  
Highly flammable.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Beaphar BV

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Fiprotec Spray 2.5 mg/ml cutaneous spray, solution for cats and dogs

### 2. Composition

Each ml contains: Fipronil 2.5 mg

Clear, colourless liquid.

### 3. Target species

Cats and dogs

### 4. Indications for use

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 veterinary medicinal product has a persistent acaricidal efficacy for up to one month against ticks, depending on the level of environmental challenge.

### 5. Contraindications

Do not use on sick or recovering 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.

### 6. Special warnings

#### Special warnings:

For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the veterinary medicinal product. Bathing or shampooing up to four times in two months has been shown not to significantly reduce the remaining effect of the veterinary medicinal product. Monthly treatment is recommended when more frequent shampooing is carried out.

The possibility that other animals in the same household can be a source of re-infection with fleas, ticks and biting lice should be considered, and these should be treated as necessary with an appropriate product.

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

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 veterinary medicinal product is not suitable for direct treatment of the environment.

Given the volume delivered by the spray pump (0.5 ml/pump) the veterinary medicinal product is very suitable for use in cats and dogs up to 5-10 kg bodyweight, depending on the length of hair (see also

section Dosage for each species, route(s) and method of administration.) but not adequate for medium and large dogs.

Special precautions for safe use in the target species:

It is important to make sure that animals do not lick each other following treatment.

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

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 veterinary medicinal product is not recommended for the treatment of species other than cats and dogs.

Puppies and kittens from 2 days of age may be safely treated.

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 cutaneous use only.

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

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

People with asthma or a known hypersensitivity (allergy) to insecticides or 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. If irritation occurs, seek medical advice.

After accidental eye contact, rinse the eye carefully with plain 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 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.

Treatment of more than one animal: Good ventilation is particularly important where several animals are to be treated. Treat the 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:

Dogs should not be allowed to swim in watercourses for 2 days after application, since fipronil may adversely affect aquatic organisms.

### Pregnancy:

Do not use on pregnant cats and dogs.

### Lactation

Dogs: the spray is safe to use on lactating dogs.

Cats: do not use on nursing cats.

### 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.

### Overdose:

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

In case of overdosing, appropriate symptomatic treatment should be started by a veterinarian.

### Major incompatibilities:

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

## **7. Adverse events**

Cats and dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):

Skin reaction<sup>1</sup> (Reddening of the skin<sup>1</sup>, Pruritus<sup>1</sup>, Alopecia<sup>1</sup>)

Hypersalivation<sup>2</sup>; Vomiting

Hyperaesthesia<sup>3</sup>, Central nervous system depression<sup>3</sup>, Neurological signs<sup>3</sup>

Respiratory signs

<sup>1</sup> Transient.

<sup>2</sup> If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

<sup>3</sup> Reversible.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medical product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

## **8. Dosage for each species, routes and method of administration**

Route of administration: Cutaneous use.

Dosage: 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 15 mg of active ingredient per kg bodyweight) i.e. 6 to 12 pump applications per kg bodyweight of the 100 ml presentation.

Short haired cats / dogs	3 ml (6 pumps) per kg body weight
Long haired cats / dogs	6 ml (12 pumps) per kg body weight
1 pump = 0.5 ml	

The 100 ml 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.

Do not overdose.

#### Method of administration:

Spray the entire body of the animal and apply from a distance of approximately 10-20 cm.

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 veterinary medicinal 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.

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.

### **9. Advice on correct administration**

### **10. Withdrawal periods**

Not applicable.

### **11. Special storage precautions**

Keep out of the sight and reach of children.

Do not store above 25 °C.

Highly flammable.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

Shelf life after first opening the bottle: 1 year. The discard date (1 year after opening) should be written in the space provided on the label.

Any product remaining after this date, should be discarded.

### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater <or household waste>.

This veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and other aquatic organisms.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

### **13. Classification of veterinary medicinal products**

Veterinary medicinal product not subject to prescription.

### **14. Marketing authorisation numbers and pack sizes**

A 100 ml bottle consisting of HDPE, fitted with a spray pump delivering 0.5 ml per pump (dip tube consisting of LDPE).

**15. Date on which the package leaflet was last revised**

<{MM/YYYY}>  
<{DD/MM/YYYY}>  
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**16. Contact details**

Marketing authorisation holder:

Beaphar B.V.  
Drostenkamp 3  
8101 BX, Raalte  
The Netherlands  
Tel: +31 (0) 572 348 834

Manufacturer responsible for batch release:

Beaphar B.V.  
Oude Linderteseweg 9  
8102 EV Raalte  
The Netherlands

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

**17. Other information**