

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Fiprotec 50 mg spot-on solution for cats

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each pipette of 0.5 ml contains:

**Active substance:** Fipronil 50.0 mg

**Excipients:**

<b>Qualitative composition of excipients and other constituents</b>	<b>Quantitative composition if that information is essential for proper administration of the veterinary medicinal product</b>
Butylhydroxyanisole (E-320)	0.100 mg
Butylhydroxytoluene (E-321)	0.050 mg
Benzyl alcohol (E-1519)	142.500 mg
Diethylene glycol monoethyl ether	

Clear colourless to slightly yellow spot-on solution.

### **3. CLINICAL INFORMATION**

#### **3.1 Target species**

Cats

#### **3.2 Indications for use for each target species**

The treatment and prevention of flea infestations (*Ctenocephalides felis*). The duration of protection against flea infestations is 5 weeks.

Treatment of tick infestations (*Ixodes ricinus*). Ticks (*Ixodes ricinus*) on the animal at time of treatment will be killed within 48 hours. Treatment does not protect against new tick infestations.

#### **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  
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 control of flea infestations in a multi-pet household, all animals in the household should be treated with a suitable insecticide.

Avoid frequent swimming or shampooing of the animal because the maintenance of effectiveness of the veterinary medicinal product has not been tested in these cases.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestations and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

### 3.5 Special precautions for use

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

For external use only.

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

Animals should be weighed accurately prior to treatment (see also section 3.3).

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 lick each other following treatment.

There may be an attachment of ticks. For this reason transmission of infectious diseases cannot be excluded.

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. Use according to a benefit/risk assessment by the responsible veterinarian.

Do not apply the veterinary medicinal product on wounds or damaged skin

Do not overdose

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

Keep the pipettes in original packaging until ready for use and dispose of used pipettes immediately.

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 known hypersensitivity to fipronil or to any of the excipients (see section 2) 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.

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

Do not smoke, drink or eat during application.

Wash hands after use.

Ingestion of the veterinary medicinal product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the veterinary medicinal product. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the doctor.

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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Do not use in non-target animals, especially not in rabbits.

The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings.

### 3.6 Adverse events

Cats

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersalivation <sup>1</sup> , Vomiting Application site skin discoloration <sup>2</sup> , Application site alopecia <sup>2</sup> , Application site pruritus <sup>2</sup> , Application site erythema <sup>2</sup> Pruritus, Alopecia 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> If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

<sup>2</sup> Transient

<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 and lactation

The safety of the veterinary medicinal product has not been established during pregnancy and lactation

Pregnancy and lactation:

Laboratory studies using fipronil have not produced any evidence of teratogenic or embryotoxic effects.

Use only according to the benefit-risk 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 use: by topical application to the skin.

Dosage:

Use 1 pipette of 0.5 ml per cat.

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

For optimal control of flea infestations the treatment schedule can be based on the local epidemiological situation.

Method of administration: Use the easy-peel corners to remove a pipette from its blister. Do not puncture the foil with scissors, knives or other sharp instruments, as this may damage the pipette inside.

Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Cut off the top of the pipette with scissors.

Part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze gently to empty its contents onto the skin, preferably at two spots, one at the base of the skull and a second 2 – 3 cm further back.

Care should be taken to avoid excessive wetting of the hair with the veterinary medicinal product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

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

The risk of experiencing adverse effects (see section 3.6) may increase with overdosing. 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.

### **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/acaricide in the phenylpyrazole family. It acts by inhibiting the GABA complex, binding to the chloride channel and thereby blocking the 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.

### **4.3 Pharmacokinetics**

#### Absorption

After topical application of the veterinary medicinal product on the cat, absorption of fipronil through the skin is negligible.

#### Distribution

After application, a concentration gradient of fipronil is set up on the fur of the animal extending from the point of application to the peripheral areas (lumbar zones, flanks).

#### Biotransformation

In 'in vitro' studies with subcellular liver fractions, the principal metabolite is the sulfone derivative of fipronil. However, this may be of limited relevance 'in vivo' as fipronil is poorly absorbed in the cat.

#### Elimination

The concentrations of fipronil on the hair decrease with time to attain a level of approximately  $1 \mu\text{g.g}^{-1}$  two months after treatment.

## **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: 2 years.  
Shelf life after first opening the immediate packaging: use immediately.

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

This veterinary medicinal product does not require any special temperature storage conditions

Keep pipette within blister and box until ready for use, in order to protect from light.

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

A blue pipette is composed of a heat-formed shell (polypropylene and acrylonitrile methyl acrylate copolymer/cyclic olefin copolymer polypropylene/polypropylene) and a film (acrylonitrile methyl acrylate copolymer/aluminium/polyester).

1, 2, 3, 6 pipettes are packed in a cardboard box.

Or

A blue pipette is composed of a heat-formed shell (polypropylene/cyclic olefin copolymer/ethylene-vinyl alcohol copolymer / polypropylene) and a film (polyethylene terephthalate/ aluminium/polypropylene).

The blue pipette is enclosed in an aluminium blister (polyethylene/ polyamide/ aluminium/polyamide/polyethylene and polyamide/aluminium/polyethylene).

1, 2, 3, 4, 6 pipettes are packed in a cardboard box.

Not all pack sizes may be marketed.

### **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**

Vm 41941/4000

## **8. DATE OF FIRST AUTHORISATION**

08 August 2014

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

February 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](http://www.gov.uk).

*Gavin Hall*

Approved: 17 March 2026