

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipnil Spot-on Solution Cat 50 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 0.5 ml pipette contains:

Active substance:

Fipronil 50 mg

Excipients:

Butylhydroxyanisole E320 0.1 mg

Butylhydroxytoluene E321 0.05 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.

Clear, pale amber solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use

Treatment of flea (*Ctenocephalides* spp.) infestations. The product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides* spp.).

Although no immediate killing effect against ticks has been demonstrated, the product has shown an acaricidal efficacy against *Dermacentor reticulatus*. If ticks of this species are present when the product is applied all the ticks may not be killed within the first 48 hours, but they will be killed within a week.

4.3 Contraindications

In the absence of available data, the product should not be used on kittens less than 2 months 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 drug reactions and even death could occur.

Do not use on animals with known hypersensitivity to the active substance or to any of excipients.

4.4 Special warnings for each target species

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 infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

The product does not prevent ticks from attaching to the animals. Once dead, ticks will often drop off the animal, but any remaining ticks may be removed with a gentle pull.

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

For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

4.5 Special precautions for use

Special precautions for use in animals

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

Do not apply the product on wounds or damaged skin.

Specific studies in cats investigating the safety of the product following repeated administration or at overdose have not been conducted due to the known safety profile of the active substance and excipients.

It is important to make sure that the 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.

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

Keep pipettes in original packaging until ready to use.

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

In the case of accidental eye contact, immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.

Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product.

In case of accidental ingestion of product seek medical advice immediately.

Do not smoke, drink or eat during application.

People with a known hypersensitivity to fipronil or any of the other ingredients should avoid contact with the product. 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.

Other precautions

The alcohol carrier may have adverse effects on painted, varnished or other household surfaces or furnishings.

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 at the application site (squamosis, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms) or vomiting have been observed after use.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

4.7 Use during pregnancy and lactation

Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this product in pregnant and lactating queens. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

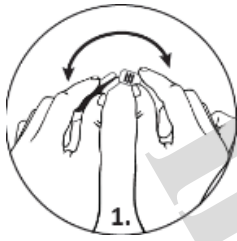
4.9 Amounts to be administered and administration route

Route of administration and dosage:

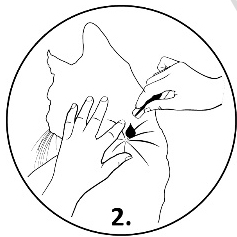
External use only.

1 pipette of 0.5 ml per cat.

Administer by topical application to the skin as follows:



Remove the pipette from the sachet. Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip.



Part the pet's coat until the skin is visible.



Place the tip of the pipette directly against the bared skin and squeeze gently to empty its contents at two points along the cat's back, preferably at the base of the head and between the shoulder blades, emptying approximately half the volume at each site. Squeeze the pipette several times to ensure dosing is complete.

Application of the solution as directed minimizes the possibility that the animal will lick the solution off.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will usually disappear within 24 – 48 hours post application.

There is little evidence available from studies with this product in cats; however, based on studies in dogs, crystals may be seen on the hair and slight scaling may occur within 24 – 48 hours after application.

Treatment schedule:

For optimal control of flea and/or tick infestation the treatment schedule can be based on the local epidemiological situation.

The minimum interval between two treatments is four weeks.

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

The toxicity of the veterinary medicinal product when administered to the skin is very low. The risk of experiencing adverse effects (see section 4.6) may increase in cases of overdose, so animals should always be treated with the correct product according to species and body weight.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use.
ATCvet code: QP53AX15

5.1 Pharmacodynamic properties

Fipronil is an insecticide and acaricide belonging to 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 cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarids. Fipronil exhibits an insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp) and acaricidal activity against ticks (*Dermacentor reticulatus*) in the cat.

Fleas will be killed within 24 h. Ticks will usually be killed within two weeks after contact with fipronil.

5.2 Pharmacokinetic particulars

In vitro, fipronil is mainly metabolised with subcellular liver fractions to its sulfone derivative. However, this may be of limited relevance 'in vivo' as fipronil is poorly absorbed in the cat. The concentrations of fipronil on the hair decrease with time.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole E320
Butylhydroxytoluene E321
Benzyl alcohol
Diethylene glycol monoethyl ether

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place in the original package.

6.5 Nature and composition of immediate packaging

A white pipette composed of a heat-formed shell of a polypropylene/cyclic olefin copolymer/polypropylene layer and a polyethylene/ethylene vinyl alcohol/polyethylene layer.

Box with 1, 2, 3, 4 or 6 pipettes in individual foil sachets.
Not all pack sizes may be marketed.

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 container.

7. MARKETING AUTHORISATION HOLDER

EU Pharmaceuticals Ltd
37 Geraldine Road
London
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UK

8. MARKETING AUTHORISATION NUMBER

Vm 39787/4009

9. DATE OF FIRST AUTHORISATION

14 December 2011

10. DATE OF REVISION OF THE TEXT

September 2021

Approved: 24/09/21

D. Austin