

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleanil 50 mg Spot-On Solution for Cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One 0.5 ml pipette contains:

Active

Fipronil	50	mg
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Excipients

Butylhydroxyanisole E320	0.1	mg
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Butylhydroxytoluene E321	0.05	mg
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For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Spot-on solution.

A clear, colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cats.

4.2 Indications for use, specifying the target species

For the treatment of infestations by fleas (*Ctenocephalides felis*). The product shows immediate insecticidal effect and persistent insecticidal activity against new infestations by adult fleas for up to 5 weeks.

The product shows acaricidal efficacy with killing effect against ticks (*Ixodes ricinus*) within 48 hours.

The product has persistent acaricidal efficacy for up to 2 weeks against ticks (*Dermacentor reticulatus*). If ticks of this species are present when the product is applied, all ticks will not be killed within the first 48 hours but they may be killed within a week.

4.3 Contraindications

In the absence of available data, the 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 drug reactions and even death could occur.
Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipients.

4.4 Special warnings for each target species

The product does not prevent ticks from attaching to the animals. If the animal has been treated prior to exposure to the ticks, the ticks will start to be killed in the first 24-48 hours after attachment. This will usually be prior to engorgement, minimising but not excluding the risk of transmission of diseases. Once dead ticks will often drop off the animal but any remaining ticks may be easily removed by a gentle pull. 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. 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. Avoid frequent swimming or shampooing of the animal because the maintenance of effectiveness of the product in these cases has not been tested.

4.5 Special precautions for use

(i) 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. 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. Do not apply the product to wounds or damaged skin.

(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 of the product with mouth and eyes should be avoided. In case of accidental eye contact, immediately and thoroughly rinse eyes with plain water. If irritation to the eyes persists contact your doctor immediately and bring with you the package leaflet. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use. Do not smoke, drink or eat during application. People with a known hypersensitivity to fipronil or excipients (see section 6.1) should avoid contact with the veterinary medicinal product.

Treated animals should not be handled until this 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.

Keep pipettes in original packaging and dispose of the used pipettes immediately.

(iii) Other precautions

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

This product is flammable. Keep away from heat, sparks, open flame or other sources of ignition.

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.

The following adverse reactions are reported very rarely:

- Transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema)
- General pruritus
- Alopecia,
- Hypersalivation,
- Reversible neurological signs (hyperaesthesia, depression, nervous signs),
- Vomiting,
- Respiratory signs

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

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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 animals. 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 interactions

None known.

4.9 Amounts to be administered and administration route

For external use only.

Animals should be weighed accurately prior to treatment.

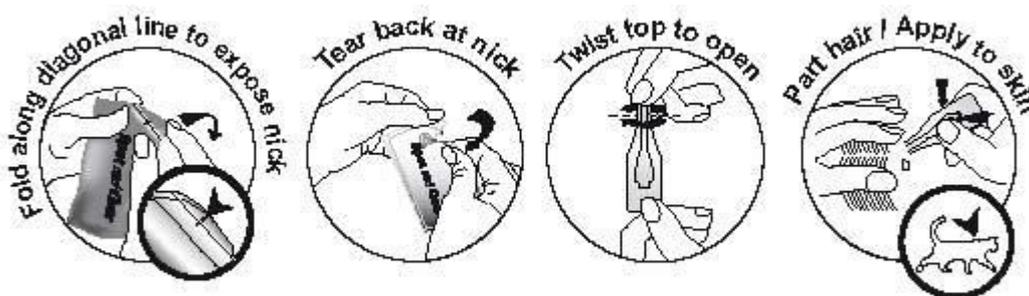
Route of administration: By topical application to the skin.

Dosage: 1 pipette of 0.5 ml per cat (approximately 7.5 – 15 mg/kg).

Method of Administration: Hold upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Break back the snap-off top from the spot-on pipette along the scored line.

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 cms further back.

To remove from sachet please use scissors or



It is important to ensure 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.

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 disappear within 24 hours post application.

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

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

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

The toxicity of the product administered to the skin is very low. The risk of experiencing adverse effects (see section 4.6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use,

ATCvet code: QP53AX15

5.1 Pharmacodynamic properties

Fipronil is an insecticide/acaricide in 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 activity against fleas (*Ctenocephalides felis*), and acaricidal activity against ticks (*Dermacentor reticulatus*) in the cat.

Newly arriving fleas are killed within 24 hours of landing on the animal.

The product is effective against flea infestation for approximately 5 weeks and against tick (*Dermacentor reticulatus*) infestations for 2 weeks, depending on the level of challenge.

5.2 Pharmacokinetic particulars

Fipronil is mainly metabolised to its sulfone derivative (RM1602), which also possesses insecticidal and acaricidal properties.

After a local application of fipronil to the cat, systemic absorption is negligible.

The concentrations of fipronil on the hair decrease with time.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)

Butylhydroxytoluene (E321)

Povidone K12

Polysorbate 80

Butanol

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: 3 years

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions. Store in the original container in order to protect from light and moisture.

6.5 Nature and composition of immediate packaging

0.5 ml pipette, moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminate and a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachet composed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.

Boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90, 120 or 150 pipettes.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/106/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 August 2013
Date of last renewal: 11 May 2018

10 DATE OF REVISION OF THE TEXT

February 2019