1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pestigon 50 mg Spot-On Solution for Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml pipette contains:

Active substance:

Fipronil 50 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole (E320)	0.1 mg
Butylhydroxytoluene (E321)	0.05 mg
Povidone K12	
Polysorbate 80	
Butyl Alcohol	
Diethylene Glycol Monoethyl Ether	

A clear, colourless to pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

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

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

The veterinary medicinal 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.

The veterinary medicinal product can be used as part of a treatment programme for Flea Allergy Dermatitis where this has been previously diagnosed by a Veterinary Surgeon.

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 drug 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

The veterinary medicinal 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.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other cats in the household are recommended.

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.

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

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 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.

Do not apply the veterinary medicinal product to wounds or damaged skin.

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

The veterinary medicinal 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, 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.

Do not smoke, drink or eat during applications.

People with known hypersensitivity to fipronil or to any of the excipients 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 used pipettes immediately.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

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

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

3.6 Adverse events

Target species: Cats.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reactions (Skin scaling[1], Alopecia[1], Pruritus[1], Erythema[1]). Generalised itching, Alopecia. Hypersalivation[2], Vomiting. Neurological signs (Hyperaesthesia[3], Depression[3], Other nervous signs[3]).

[1] Transient.
[2] If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.
[3] 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 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 using fipronil have not shown any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this product in pregnancy and lactating animals. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

3.8 Interaction with other medicinal products and other forms of interaction

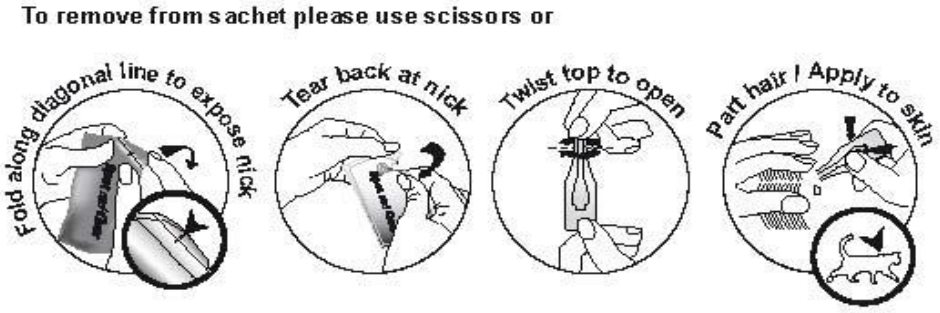
None known.

3.9 Administration routes and dosage

Spot-on use.
For external use only.
Animals should be weighted 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 cm further back.



It is important to ensure 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.

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.

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.

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

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

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 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 veterinary medicinal 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.

4.3 Pharmacokinetics

Fipronil is mainly metabolised to its sulfone derivative (RM 1602), 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

0.5 ml pipette, moulded form 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.

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 to 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

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/098/001

8. DATE OF FIRST AUTHORISATION

06/07/2012

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

14/08/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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