SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pestigon 134 mg Spot-On Solution for Medium Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 1.34 ml pipette contains:

Active substance:

Fipronil	134 mg

Excipients:

Butylhydroxyanisole (E320)	0.268 mg
Butylhydroxytoluene (E321)	0.134 mg

For the 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

Dogs.

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 8 weeks.

The product has a persistent acaricidal efficacy against *Ixodes ricinus* for up to 2 weeks, *Rhipicephalus sanguineus* for up to 3 weeks and *Dermacentor reticulatus* for up to 4 weeks. If ticks of these 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 product can be used as part of a treatment programme for Flea Allergy Dermatitis where this has been previously diagnosed by a Veterinary Surgeon.

4.3 Contra-Indications

Do not use in dogs weighing less than 10 kg.

In the absence of available data, the product should not be used in puppies less than 8 weeks old.

Do not use in sick (systemic diseases, fever…) or convalescent animals.

Do not use in rabbits, as adverse reactions and even death could occur.

This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

Do not use in cases of known hypersensitivity to the active 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, but ticks may be killed in the first 24-48 hours after attachment prior to full engorgement and therefore minimising the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may easily be 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 dogs in the household are recommended.

For optimal control of flea infestation in multi-pet household, all dogs and cats in the house 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 on 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 the mouth and eyes should be avoided.

In cases of accidental eye contact, immediately and thoroughly rinse the eye with plain water. If eye irritation persists seek medical advice and show the package leaflet or the label to a physician.

People with a known hypersensitivity to fipronil or excipients (section 6.1) should avoid contact with the veterinary product.

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.

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.

(iii) Other precautions

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

The alcohol carrier may have adverse effect 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.

Among the extremely rare suspected adverse reactions, transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus,

erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs 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, 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 Interaction

None known.

4.9 Amounts to be Administered and Administration Route

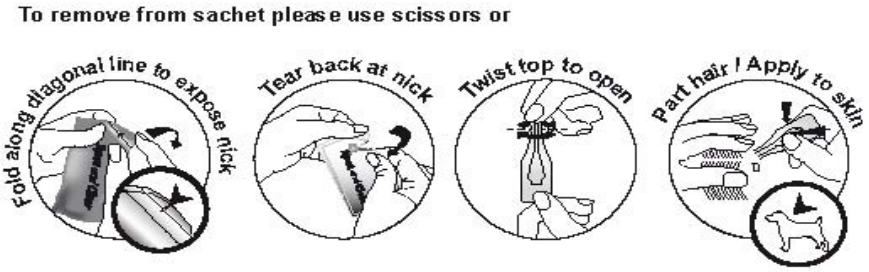
Route of administration: By topical application to the skin.

For external use only. Apply the product directly to the skin based on weight of the animal.

Animals should be weighed accurately prior to treatment.

Dosage –
1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight.

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 at one or two spots to empty its contents onto the skin.



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 the 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 48 hours post application.

For the optimal control of infestation by flea and or/tick the treatment schedule can be based on 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

No adverse effects were observed in target animal safety studies in 8 week old puppies, growing dogs and dogs weighing circa 2kg treated on 3 occasions at five times the recommended dose. 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 Periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Ectoparasiticides for topical use.
ATC Vet 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 cell

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 (*Rhipicephalus sanguineus,Dermacentor reticulatus, Ixodes ricinus)* in the dog.

Newly arriving fleas are killed within 24 hours of landing on the animal. Ticks if already present at the time of application of the product, may not always be killed in the first 48 hours, however will be killed within 9 days post treatment.

The product is effective against flea infestation (*Ctenocephalides felis*) for approximately 8 weeks and against tick infestations for up to 4 weeks (see indications for use), depending on the tick species and the level of challenge.

5.2 Pharmacokinetic Particulars

After a local application of fipronil to the dog, it is slightly absorbed through the skin. Low levels of fipronil may be detected in the plasma, with a very high variability between dogs. After application, there is a good distribution of the chemical on the hair, presenting a good gradient of concentration between the application zone and the peripheral area.

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

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
Butyl Alcohol
Diethylene Glycol Monoethyl Ether

6.2 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

1.34 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 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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4326

9. DATE OF FIRST AUTHORISATION

06 July 2012

10. DATE OF REVISION OF THE TEXT

June 2017

Approved 13 July 2017