PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90, 120 or 150 pipettes containing 1.34 ml pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pestigon 134 mg Spot-On Solution for Medium Dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One 1.34 ml pipette contains:
134 mg Fipronil
0.268 mg Butylhydroxyanisole (E320)
0.134 mg Butylhydroxytoluene (E321)

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

Carton of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90, 120 or 150 pipette(s) containing 1.34 ml.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

For the treatment of infestations by fleas and ticks.

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 may not be killed within the first 48 hours but they will 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For dogs weighing 10-20 kg.
Do not remove the pipette from the sachet until required for use.
For external use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: mm/yyyy

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

IE - POM
Prescription Only Medicine

UK - POM-V
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

(EU)
Norbrook Laboratories (Ireland) Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

VM 02000/4326

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMEMEDIATE PACKAGING UNITS

Sachet for 1.34 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pestigon 134 mg Spot-On Solution for Medium Dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One 1.34 ml pipette contains 134 mg Fipronil

3. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1.34 ml

4. ROUTE(S) OF ADMINISTRATION

By topical application to the skin.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP: mm/yyyy

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

9. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1.34 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pestigon

2. STRENGTH

134 mg

3. NAME OF MARKETING AUTHORISATION HOLDER

Norbrook

4. EXPIRY DATE

mm/yyyy

5. BATCH NUMBER

XXXX XXX

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

<Pictogram of dog>

7. PHARMACEUTICAL FORM

<Pictogram of spot-on pipette>

8. VOLUME

1.34 ml

9. TARGET ANIMAL WEIGHT RANGE

10 – 20 kg

PACKAGE LEAFLET:

Pestigon 134 mg Spot-On Solution for Medium Dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
(EU)
Norbrook Laboratories (Ireland) Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

Manufacturer responsible for batch release
Norbrook Laboratories Limited,
Station Works,
Newry,
Co. Down,
BT35 6JP,
United Kingdom

Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pestigon 134 mg Spot-On Solution for Medium Dogs
Fipronil

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One 1.34 ml pipette contains:
134 mg Fipronil
0.268 mg Butylhydroxyanisole (E320)
0.134 mg Butylhydroxytoluene (E321)

A clear, colourless to pale yellow solution.

4. INDICATIONS

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 may not be killed within the first 48 hours but they will 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.

5. CONTRAINDICATIONS

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.

6. ADVERSE REACTIONS

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).

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Route of administration: By topical application to the skin.

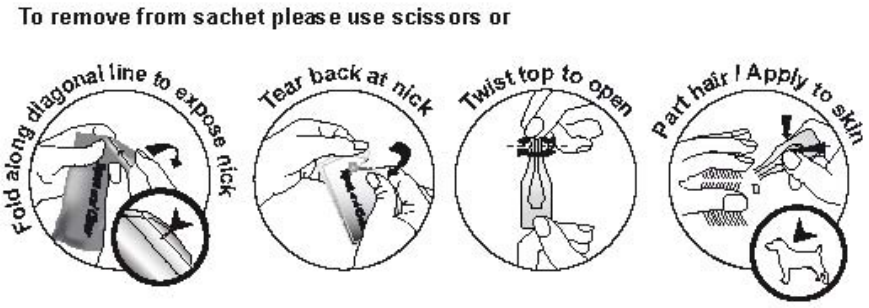
For external use only. Apply the product directly to the skin based on weight of the animal.

Do not remove the pipette from the sachet until required for use.

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.



9. ADVICE ON CORRECT ADMINISTRATION

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.

Animals should be weighed accurately prior to treatment.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This medicinal product does not require any special temperature storage conditions.
Store in the original container in order to protect from light and moisture.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNINGS

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.

Special precautions for use in animals

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

For external use only

Animals should be weighed accurately prior to treatment.

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.

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 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 other ingredients 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.

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.

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.

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 may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

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

For Animal Treatment Only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2019

15. OTHER INFORMATION

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Prescription Only Medicine

UK - POM-V
To be supplied only on veterinary prescription

ManA 2000

Mode of Action
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

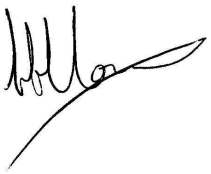
post-synaptic transfer of chloride ions across the membrane. This results in uncontrolled activity of the central nervous system and death in insects and acarids.

Package Information

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.



Approved 31 July 2019