ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90, 120 or 150, 0.5 ml pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiproclear 50 mg Spot-On Solution for Cats
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One 0.5 ml pipette contains:
50 mg Fipronil
0.1 mg Butylhydroxyanisole E320
0.05 mg Butylhydroxytoluene E321

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90, 120 or 150, 0.5 ml pipettes.

5. TARGET SPECIES

Cats.

6. INDICATION(S)

Ticks and Fleas.

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.

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 cats weighing more than 1 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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: mm/yyyy

11. SPECIAL 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.
NFA-VPS

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

(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

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

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBERS

Vm 02000/4354

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet for 0.5 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiproclear 50 mg Spot-On Solution for Cats
Fipronil

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One 0.5 ml pipette contains 50 mg Fipronil.

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

0.5 ml

4. ROUTE(S) OF ADMINISTRATION

By topical application to the skin.

5. WITHDRAWAL PERIOD

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.

NFA-VPS

Vm 02000/4354

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

0.5 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiproclear

2. STRENGTH

50 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 a cat>

7. PHARMACEUTICAL FORM

<Pictogram of a spot-on pipette>

8. VOLUME

0.5 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Fiproclear 50 mg Spot-On Solution for Cats

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) Limited
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

Fiproclear 50 mg Spot-On Solution for Cats
Fipronil

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

One 0.5 ml pipette contains:
50 mg Fipronil
0.1 mg Butylhydroxyanisole E320
0.05 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 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.

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

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 known hypersensitivity to the active substance or to any of the excipients

6. ADVERSE REACTIONS

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 usingthe following convention:

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

If you notice any side effects even those already listed in this package leaflet, or you think the medicine has not worked please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

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

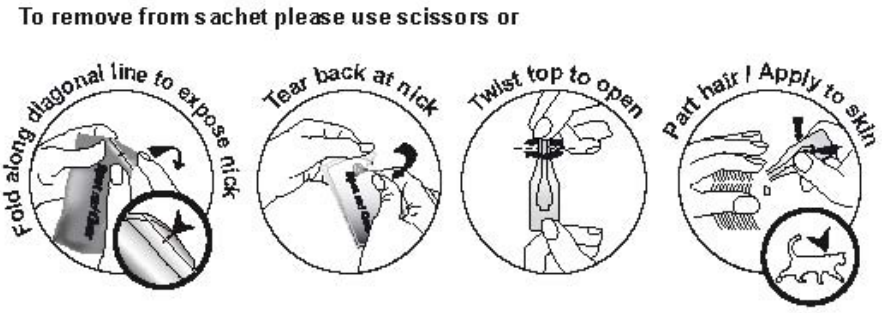
For external use only.

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.



9. ADVICE ON CORRECT ADMINISTRATION

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.

Animals should be weighed accurately prior to treatment.

10. WITHDRAWAL PERIOD

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. 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.

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

There may be an attachment of ticks. For this reason transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

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.

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.

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 to 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 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 other ingredients 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.

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.

No studies have been carried out on pregnant or lactating cats using this veterinary medicinal product, therefore its use during pregnancy and lactation should only occur after a relevant benefit-risk analysis made by the treating veterinarian.

Other precautions

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

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.

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

October 2022

15. OTHER INFORMATION

NFA-VPS
Non-Food Animal Medicine – Veterinarian, Pharmacist, Suitably Qualified Person

ManA 2000
Vm 02000/4354

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
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.

Distributed by:
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Approved 28 October 2022