

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton of 1, 2, 3, 4 or 6 pipettes containing 0.5 ml pipettes**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Norbrook Fipronil and (S)-Methoprene 50 mg / 60 mg spot-on solution for cats and ferrets (IE)  
Fleanil Duo 50 mg / 60 mg spot-on solution for cats and ferrets (UK)  
fipronil  
S-methoprene

### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

#### **What is in this medicine?**

One 0.5 ml pipette contains:

50 mg fipronil  
60 mg (S)-methoprene  
0.10 mg butylhydroxyanisole (E320)  
0.05 mg butylhydroxytoluene (E321)

### **3. PHARMACEUTICAL FORM**

Spot-on solution.

### **4. PACKAGE SIZE**

1, 2, 3, 4 or 6 0.5 ml pipettes.

### **5. TARGET SPECIES**

Cats and ferrets.

### **6. INDICATION(S)**

#### **What is this medicine used for?**

In cats:

To be used against infestations with fleas, alone or in association with ticks and/or biting lice.

- Kills fleas (*Ctenocephalides* spp.) for up to 4 weeks and prevents eggs, larvae and pupae from exposed fleas from developing for up to 6 weeks.
- Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*) on treated cats for up to 2 weeks.

- Kills biting lice (*Felicola subrostratus*).

In ferrets:

To be used against infestations with fleas, alone or in association with ticks.

- Kills fleas (*Ctenocephalides* spp.) and prevents against new infestations with adult fleas for up to 4 weeks. The product also prevents the development of eggs and the emergence of developing fleas.
- Kills ticks (*Ixodes ricinus*) on treated ferrets for 4 weeks.

Read the package leaflet carefully before each use. Keep the leaflet and any unopened sachets in the carton until required.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

### How do I use this medicine?

**For external use only.** Spot-on use.

For cats weighing more than 1 kg. For ferrets aged 6 months and older.

Read the package leaflet before use.

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.

Always leave a minimum period of 4 weeks between treatments.

## 8. WITHDRAWAL PERIODS

Not applicable.

## 9. SPECIAL WARNING(S), IF NECESSARY

### Do not use this product:

- On kittens less than 8 weeks old and/or weighing less than 1 kg.
- On ferrets less than 6 months old.
- On sick (e.g. systemic diseases, fever) or convalescent animals.
- On rabbits, as adverse drug reactions including death could occur.
- On species other than cats and ferrets.
- If your pet is hypersensitive (allergic) to the active substance or to any of the excipients.

The safety of the product for kittens of less than 8 weeks of age in contact with a treated female cat (queen) is not documented. Special care should therefore be taken if treating cats with kittens.

The safety of the veterinary medicinal product has not been established in ferrets during pregnancy and lactation.

### User Safety Warnings

**Please read before every use**

This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided. In case of accidental eye contact, immediately and thoroughly rinse the eyes with clean water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician. If contact with the skin occurs, wash hands with soap and water.

People with a known hypersensitivity (allergy) to Fipronil, (S)-Methoprene, alcohol or excipients should avoid contact with the veterinary medicinal 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.

Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. In case of accidental ingestion of product, seek medical advice immediately.

Treated animals should not be handled until the 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 are not allowed to sleep with owners, especially children.

Please read the package leaflet provided before every use.

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

## **10. EXPIRY DATE**

EXP: mm/yyyy

## **11. SPECIAL STORAGE CONDITIONS**

### **How should this medicine be stored?**

Store in the original package in order to protect from light and moisture.

Keep pipettes in the original packaging until ready to use.

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

Disposal: Dispose of waste materials in accordance with local requirements. Fipronil and (S)-methoprene may adversely affect aquatic organisms, do not contaminate ponds, waterways or ditches with the product or empty containers.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

**For animal treatment only.**

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**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**

Norbrook Laboratories Limited  
Station Works  
Camlough Road  
Newry  
Co. Down  
BT35 6JP  
United Kingdom

**16. MARKETING AUTHORISATION NUMBER**

Vm 02000/4412

**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**

Norbrook Fipronil and (S)-Methoprene 50 mg / 60 mg spot-on solution for cats and ferrets  
Fleanil Duo 50 mg / 60 mg spot-on solution for cats and ferrets (UK)  
fipronil  
S-methoprene

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

**What is in this medicine?**

One 0.5 ml pipette contains:  
50 mg fipronil  
60 mg (S)-methoprene

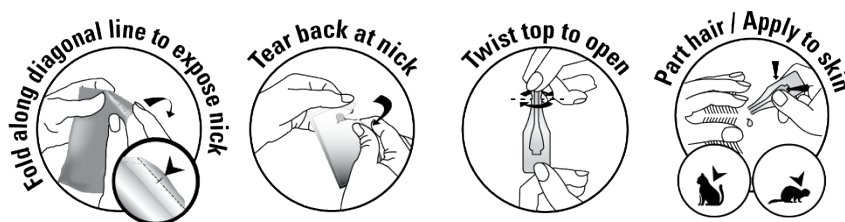
**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

0.5 ml

**4. ROUTE(S) OF ADMINISTRATION**

**How do I use this medicine?**

Spot-on use.  
Only remove pipette from sachet immediately prior to use.  
<Pictogram of a spot-on pipette>



**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.

Cat <Pictogram of a cat>. Ferret <Pictogram of a ferret>

**9. MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited.



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**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**0.5 ml pipette/blister**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Norbrook Fipronil and (S)-Methoprene  
Fleanil Duo 50 mg / 60 mg spot-on solution for cats and ferrets (UK)

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Norbrook

**3. EXPIRY DATE**

mm/yyyy

**4. BATCH NUMBER**

XXXX XXX

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

<Pictogram of a cat> <Pictogram of a ferret>

**6. PHARMACEUTICAL FORM**

<Pictogram of a spot-on pipette>

**7. Active Content**

50 mg / 60 mg

**8. VOLUME**

0.5 ml



**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**

**Norbrook Fipronil and (S)-Methoprene 50 mg / 60 mg spot-on solution for cats and ferrets**

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

Norbrook Laboratories Limited  
Station Works  
Camlough Road  
Newry  
Co. Down  
BT35 6JP  
United Kingdom

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Norbrook Fipronil and (S)-Methoprene 50 mg / 60 mg spot-on solution for cats and ferrets  
Fleanil Duo 50 mg / 60 mg spot-on solution for cats and ferrets (UK)  
fipronil  
S-methoprene

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

One 0.5 ml pipette contains:

**Active substances:**

Fipronil .....	50 mg
(S)-methoprene .....	60 mg

**Excipients:**

Butylhydroxyanisole (E320) .....	0.10 mg
Butylhydroxytoluene (E321) .....	0.05 mg

A clear, yellow solution.

**4. INDICATION(S)**

The product is used for the treatment of infestations by fleas, ticks and biting lice in cats and for the treatment of infestations by fleas and ticks in ferrets.

In cats treatment with the product:

- Kills fleas (*Ctenocephalides* spp.) for up to 4 weeks and prevents eggs , larvae and pupae from exposed fleas from developing for up to 6 weeks.

- Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*) on treated cats for up to 2 weeks.
- Kills biting lice (*Felicola subrostratus*).

In ferrets treatment with the product:

Kills fleas (*Ctenocephalides* spp.) and prevents against new infestations with adult fleas for up to 4 weeks. The product also prevents the development of eggs and the emergence of developing fleas.

Kills ticks on treated ferrets (*Ixodes ricinus* for 4 weeks).

## 5. CONTRAINDICATIONS

Do not use the product on kittens less than 8 weeks old and/or weighing less than 1 kg. Do not use the product on ferrets less than 6 months old.

Do not use on sick (e.g. fever) or convalescent animals.

Do not use in rabbits, as adverse drug reactions with even mortality could occur.

Do not use the product in species other than cats and ferrets.

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

Do not use simultaneously with other flea products which are applied directly on to the animal.

## 6. ADVERSE REACTIONS

Cats

In very rare cases, temporary skin reactions on the application site (skin discoloration, local hair loss, itching, redness) and general itching or hair loss have been reported after use. Excessive salivation, reversible nervous signs (increased sensitivity to stimulation, depression, other nervous signs) or vomiting have also been observed after use.

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).

If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

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

## 7. TARGET SPECIES

Cats and ferrets.

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

### Dosage:

One pipette of 0.5 ml per cat, corresponding to a minimum recommended dose of 5 mg/kg for fipronil and 6 mg/kg for (S)-methoprene.

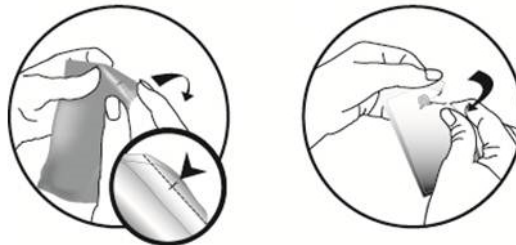
One pipette of 0.5 mL per ferret corresponding to a dose of 50 mg for fipronil and 60 mg for (S)-methoprene per ferret.

Do not overdose.

Route of administration: External use only, spot-on use.  
Only remove pipette from sachet immediately prior to use.

### Method of Administration:

Remove the pipette from the outer sachet using scissors or fold along diagonal line to expose nick; tear back at nick.



Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Twist or snap back the tip.



Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.



Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

## **9. ADVICE ON CORRECT ADMINISTRATION**

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.

Avoid contact with the animal's eyes

Always leave a minimum period of 4 weeks between treatments

## **10. WITHDRAWAL PERIOD**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store in the original package in order to protect from light and moisture.

This veterinary medicinal product does not require any special temperature storage conditions.

Do not use after the expiry date stated on the sachet and carton.

## **12. SPECIAL WARNING(S)**

**For Animal Treatment Only.**

**Special warnings for each target species:**

Bathing and/or shampooing should be avoided as no information on the effect of bathing or the use of a shampoo on the effectiveness of the product in cats or ferrets is available.

There may be an attachment of a few ticks. For this reason, transmission of infectious diseases cannot be completely excluded if conditions are unfavourable. When treating infestations of fleas, all in-contact animals should be treated with an appropriate product at the same time.

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. Bathing and/or shampooing should be avoided as the effect of bathing or the use of a shampoo on the effectiveness of the product in cats or ferrets is unknown.

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

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

This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided. In case of accidental eye contact, immediately and thoroughly rinse the eyes with clean water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician. If contact with the skin occurs, wash hands with soap and water.

People with a known hypersensitivity (allergy) to Fipronil, (S)-Methoprene, alcohol or excipients should avoid contact with the veterinary medicinal 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.

Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. In case of accidental ingestion of product, seek medical advice immediately.

Treated animals should not be handled until the 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 are not allowed to sleep with owners, especially children.

#### **Pregnancy and Lactation:**

Cats: The product can be used during pregnancy.

Consult a veterinary surgeon before using the product on animals in contact with kittens that are less than 8 weeks old.

**Ferrets:** Studies have not been carried out with this product in pregnant and lactating animals.

Consult a veterinary surgeon before using the product on such animals.

#### **Overdose (symptoms, emergency procedures, antidotes):**

In cats:

The risk of experiencing adverse effects (see section 6. Adverse Reactions) may increase with overdosing.

Itching may occur following treatment.

Overdose application of the product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

In ferrets: Ferrets aged 6 months and older and treated once every 2 weeks for four treatments, at five times the recommended dose, body weight loss was observed in some animals.

#### **Other precautions**

Fipronil may adversely affect aquatic organisms. Treated animals should not be allowed to enter 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.

### 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 product should be disposed of in accordance with local requirements.

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

### 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

### 15. OTHER INFORMATION

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#### **Packaging 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 or 6 pipettes. Each pipette is individually sealed in a foil sachet.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 22 October 2020

