ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 1, 2, 3, 4, 6, 8, 12 or 24 pipettes containing 0.5 ml pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiproclear Combo 50 mg / 60 mg spot-on solution for cats and ferrets

fipronil
S-methoprene

2. STATEMENT OF ACTIVE SUBSTANCES

One 0.5 ml pipette contains:

50 mg fipronil
60 mg (S)-methoprene

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1, 2, 3, 4, 6, 8, 12 or 24, 0.5 ml pipettes.

5. TARGET SPECIES

Cats and ferrets.

6. INDICATION(S)

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

- Elimination of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for six weeks after application.
- Elimination of ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 2 weeks against ticks (based on experimental data).
- Elimination of biting lice (*Felicola subrostratus*).

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

- Elimination of fleas (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 weeks. Prevention of the

multiplication of fleas by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas.
- Elimination of ticks (*Ixodes ricinus*). The product has a persistent acaricidal efficacy for 4 weeks against ticks (based on experimental data).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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.

8. WITHDRAWAL PERIODS

Not applicable.

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 package 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.

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
Newry
Co. Down
BT35 6JP
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4407

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 Combo 50 mg / 60 mg spot-on solution for cats and ferrets

fipronil
S-methoprene

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

5. WITHDRAWAL PERIODS

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.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

0.5 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiproclear Combo

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:
Fiproclear Combo 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

Marketing authorisation holder :
(UK-NI) Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

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

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

Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiproclear Combo 50 mg / 60 mg spot-on solution for cats and ferrets

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:
- Eliminates fleas (*Ctenocephalides* spp.) and prevents against new infestations with adult fleas for up to 4 weeks. The product also inhibits the development of eggs and the emergence of developing fleas for six weeks after application.
- Eliminates ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 2 weeks against ticks (based on experimental data).
- Eliminates biting lice (*Felicola subrostratus*).

In ferrets treatment with the product:
- Eliminates fleas (*Ctenocephalides* spp.) and prevents against new infestations with adult fleas for up to 4 weeks. The product also inhibits the development of eggs and the emergence of developing fleas.
- Eliminates ticks (*Ixodes ricinus*). The product has a persistent acaricidal efficacy for 4 weeks against ticks (based on experimental data).

5. CONTRAINDICATIONS

The product should not be used on kittens less than 8 weeks old and/or weighing less than 1 kg. The product should not be used 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.
The use of the product is not recommended in non-target species.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

Cats
Among the very rare suspected adverse reactions, temporary skin reactions on the application site (scaling, 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.

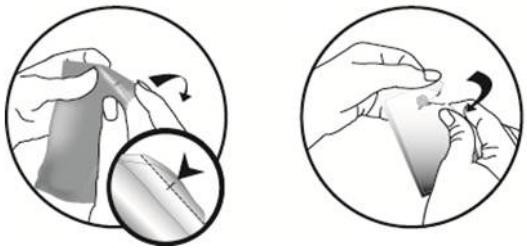
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

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.

No data on the effect of bathing/shampooing on the efficacy of the product in cats and ferrets are available. However, based on information available for dogs shampooed as from 2 days after application of the product, it is not recommended to bath animals within 2 days after application of the product.

The minimum treatment interval is 4 weeks.

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 this veterinary medicinal product after the expiry date which is stated on the sachet and carton. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

For Animal Treatment Only.

There may be an attachment of single ticks. For this reason a transmission of tick-borne 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 warnings for each target species:
The potential for harmful effects of the product on kittens of less than 8 weeks of age in contact with a treated queen has not been documented. Special care should be taken in this case.

Special precautions for use in animals:
Avoid contact with the animal's eyes.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided. Do not smoke, drink or eat during the application. 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 to insecticides or alcohol should avoid contact with the veterinary medicinal product.

Wash hands after use.

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.

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

Pregnancy and Lactation:
Cats: The product can be used during pregnancy. For treatment during the lactating period, see the "Special warnings for each target species" section of this package leaflet.

Ferrets: Laboratory studies in cats have not produced any evidence of detrimental effects during pregnancy. The safety of the veterinary medicinal product however has not been established in ferrets during pregnancy and lactation. Seek specific advice from a veterinarian prior to use of this product if your ferret is pregnant.

Overdose (symptoms, emergency procedures, antidotes):
In cats: No undesirable effects were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months.
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.

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

March 2022

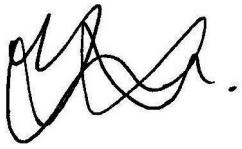
15. OTHER INFORMATION

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, 6, 8, 12, or 24 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: 13 April 2022