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 pipettes containing 1.34 ml pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiproclear Combo 134 mg / 120.6 mg spot-on solution for medium dogs

fipronil
S-methoprene

2. STATEMENT OF ACTIVE SUBSTANCES

One 1.34 ml pipette contains:

134 mg fipronil
120.6 mg (S)-methoprene

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

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

- Treatment of flea infestations (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. Prevention of the multiplication of fleas by inhibiting of the development of eggs (ovicidal activity) and larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for eight weeks after application.
- Treatment of tick infestations (*Ixodes ricinus*, *Dermacentor variabilis, Dermacentor reticulatus*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 4 weeks against ticks.
- Treatment of infestations with biting lice (*Trichodectes canis*).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

External use only. Spot-on use. For dogs weighing 10 to 20 kg.
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

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

(UK-NI) Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4409

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet for 1.34 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiproclear Combo 134 mg / 120.6 mg spot-on solution for medium dogs

fipronil
S-methoprene

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One 1.34 ml pipette contains:

134 mg fipronil
120.6 mg (S)-methoprene

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

1.34 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.
Dog <Pictogram of a dog>.

9. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1.34 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 dog>

6. PHARMACEUTICAL FORM

<Pictogram of a spot-on pipette>

7. Active Content

134 mg / 120.6 mg

8. VOLUME

1.34 ml

9. TARGET ANIMAL WEIGHT RANGE

10 – 20 kg

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Fiproclear Combo 134 mg / 120.6 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
(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 134 mg / 120.6 mg spot-on solution for medium dogs

fipronil
S-methoprene

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

Each pipette of 1.34 ml contains:

Active substances:
Fipronil .....134 mg
(S)-methoprene.....120.6 mg

Excipients:
Butylhydroxyanisole (E320) .....0.27 mg
Butylhydroxytoluene (E321).....0.13 mg

A clear, yellow solution.

4. INDICATION(S)

For the treatment of dogs weighing 10 to 20 kg bodyweight:

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

In dogs treatment with the product:

- Eliminates fleas (*Ctenocephalides* spp.) and prevents against new infestations with adult fleas for up to 8 weeks. The product also inhibits the development of eggs and the emergence of developing fleas for eight weeks after application.
- Eliminates ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 4 weeks against ticks.
- Eliminates biting lice (*Trichodectes canis*).

5. CONTRAINDICATIONS

The product should not be used on puppies less than 8 weeks old.
Do not use on sick (e.g. fever) or convalescent animals.
Do not use in rabbits, as adverse reactions with even mortality could occur.
The use of the product is not recommended in non-target species.
This product is specifically developed for dogs. Do not use in cats and ferrets, as this could lead to overdosing.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Among the very rare suspected adverse reactions, 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), vomiting or respiratory symptoms 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

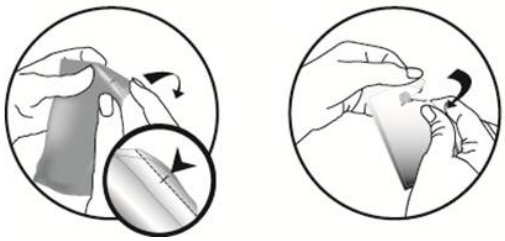
Dogs.

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

Dosage: One pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg, corresponding to a minimum recommended dose of 6.7 mg/kg for fipronil and 6 mg/kg for (S)-methoprene.

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.

Bathing/immersion in water within 2 days after application of the product and more frequent bathing than once a week should be avoided as no study has been performed to investigate how this affects the efficacy of the product. Emollient shampoos can be used prior to treatment, but reduce the duration of protection against fleas to approximately 5 weeks when used weekly after application of the product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study.

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. This expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

For Animal Treatment Only.

There may be an attachment of a few ticks. For this reason a transmission of tick-borne diseases cannot be completely excluded if conditions are unfavorable.

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.

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

Special precautions for use in animals:
Avoid the 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:
The product can be used during pregnancy and lactation.

Overdose (symptoms, emergency procedures, antidotes):
No adverse effects were observed in target animal safety studies in 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated once 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.

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

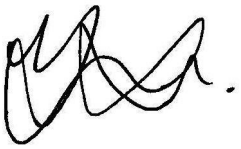
15. OTHER INFORMATION

Packaging Information:
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. 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