

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BASE VIAL LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLEANIL 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs [IE, AT, BE, CZ, DE, HU, NL, PT, SK, UK]

FLEANIL Vet 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs [DK, SE]

FIPROCLEAR 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs [FR, IT, PL, ES]

Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains 2.5 mg of fipronil

3. PHARMACEUTICAL FORM

Cutaneous spray, solution

4. PACKAGE SIZE

100 ml, 250 ml and 500 ml

5. TARGET SPECIES

Dogs and Cats

6. INDICATION(S)

Only for those countries where the product is available without prescription.

Fleas, ticks and biting lice.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Shelf-life after first opening the immediate packaging: 6 months

Once opened use by: _____

11. SPECIAL STORAGE CONDITIONS

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

Disposal: Read the 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
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

17. MANUFACTURER’S BATCH NUMBER

B.N.:

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EXPANDING VIAL LABEL TEXT – PAGE 1

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8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

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For animal treatment only.

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Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrosk Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

17. MANUFACTURER’S BATCH NUMBER

B.N.:

PACKAGE LEAFLET

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FIPROCLEAR 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs [FR, IT, PL, ES]

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

Marketing authorisation holder and manufacturer responsible for batch release:

Norbroom Laboratories Limited,
Station Works,
Newry,
Co. Down,
BT35 6JP,
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLEANIL 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs [IE, AT, BE, CZ, DE, HU, NL, PT, SK, UK]

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FIPROCLEAR 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs [FR, IT, PL, ES]

Fipronil

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

Each ml contains:

Active substance:

Fipronil 2.5 mg

Cutaneous spray, solution.

A clear, colourless solution

4. INDICATIONS

Treatment of flea (*Ctenocephalides* spp.) and tick (*Ixodes ricinus*, *Rhipicephalus sanguineus*) infestations in dogs and cats.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

Insecticidal efficacy against new infestations with adult fleas persists for up to 2 months in cats and up to 3 months in dogs, depending on environmental challenge.

The product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.

5. CONTRAINDICATIONS

Do not use the product in rabbits, as adverse reactions and even death could occur. Do not use on sick (systemic diseases, fever...) or convalescent animals.

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

6. ADVERSE REACTIONS

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

Among the extremely rare suspected adverse reactions, transient skin reactions including inflammation, itching or hair loss have been reported after use. Exceptionally, drooling saliva, reversible neurological signs (hypersensitivity, depression, nervous signs), vomiting or respiratory signs have been observed after use. Do not overdose.

Start an appropriate symptomatic treatment in case of overdosing.

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

7. TARGET SPECIES

Dogs and cats.

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

Method of administration:

Spray the entire body of the animal, and apply from a distance of approximately 10-20 cm. Apply against the lay of the hair and make sure that the entire coat of the animal is dampened. Ruffle the coat, especially in long haired animals, so that the product penetrates down to the skin. For treatment of the head region, and when treating young or nervous pets, application may be carried out by spraying onto a gloved hand and rubbing the product into the coat. Allow to dry naturally. Do not towel dry.

Dosage:

In order to dampen the coat down to the skin, depending on the length of hair, apply 3 to 6 ml per kg bodyweight, (7.5 to 15 mg of active ingredient per kg bodyweight) i.e. 6 to 12 pump applications per kg bodyweight of the 100 ml presentation, or 2 to 4 pump applications per kg bodyweight of the 250 ml and 500 ml presentations.

Dosage can be determined as follows:

Short hair cat/dog i.e. hair length less than 2 cm.

Dose: 3-4 ml/kg bodyweight

100 ml bottle: 6 pump applications per kg bodyweight

250 ml and 500 ml bottle: 2 pump applications per kg bodyweight

Medium hair dog/long hair cat i.e. hair length 2 – 4 cm.

Dose: 4-5 ml/kg bodyweight

100 ml bottle: 9 pump applications per kg bodyweight

250 ml and 500 ml bottle: 3 pump applications per kg bodyweight

Long hair dog/longer hair cat i.e. hair length greater 4 cm.

Dose: 5-6 ml/kg bodyweight

100 ml bottle: 12 pump applications per kg bodyweight

250 ml and 500 ml bottle: 4 pump applications per kg bodyweight

The 100 ml pack contains approximately 8 treatments for a short haired medium sized cat (4 kg). The 250 ml pack contains approximately 4 treatments for a short haired medium sized dog (20 kg). The 500ml pack contains approximately 8 treatments for a short haired medium sized dog (20 kg).

Note length of hair (short, medium, long) is given as an approximate guide and depends on the species. It is important to ensure that the entire coat of the animal is dampened, down to the skin, especially in long haired animals.

Puppies and kittens from 2 days of age may be safely treated with the product; however, particular care should be taken to obtain accurate body weights for young animals so that the number of pumps required can be accurately calculated using the above guidance.

A Practical Guide To Treatment With The Product

The table below is a guide to show the approximate number of pumps required for the treatment of cats and dogs according to body weight. The appropriate number of pumps should be calculated using the above guidance.

It is very important to weigh very small animals accurately, in particular puppies and kittens, and to calculate the dose as described in the dosage section above.

	Short hair Dogs and cats (Hair length <2cm)	Medium Hair Dogs/ Long hair cats (Hair length 2-4cm)	Long Hair dogs and cats (Hair length >4cm)
100 ml pack (Delivers 0.5 ml of product per pump)			
Cats/Toy breeds (4 kg) e.g. Toy Poodle	24 pumps	36 pumps	48 pumps
Small breeds (8 kg) e.g. Terrier	48 pumps	72 pumps	96 pumps
250 ml pack (Delivers 1.5 ml of product per pump)			
Cats and small breeds of dogs (5 kg)	10 pumps	15 pumps	20 pumps
Medium Breeds (15 kg) e.g. Spaniel	30 pumps	45 pumps	60 pumps
Large breeds (30 kg) eg Labrador	60 pumps	90 pumps	120 pumps
500 ml pack (Delivers 1.5 ml of product per pump)			
Cats and small breeds of dogs (5 kg)	10 pumps	15 pumps	20 pumps
Medium Breeds (15 kg) e.g. Spaniel	30 pumps	45 pumps	60 pumps
Large breeds (30 kg) e.g. Labrador	60 pumps	90 pumps	120 pumps

9. **ADVICE ON CORRECT ADMINISTRATION**

For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the product. [Refer also to the “Other Information” section of this leaflet].

The treatment:

1. Treat your pet in a well ventilated room or outdoors. Put on a pair of protective PVC or nitrile gloves. A waterproof apron is also recommended to protect clothing.
2. Check the spray pump by depressing the nozzle. It should release a cone of spray. Do not breathe spray.
3. Restrain your pet to hold it still. Putting a collar on your pet will help you to hold it more firmly.
4. Ruffle the pet’s dry coat against the lay of the hair, in preparation for spraying.
5. Hold the dispenser vertically, 10-20 cm (4-7 inches) away from the coat, then apply the spray, dampening the coat, right down to the skin. A guide to the approximate number of pumps you will require can be found on the preceding section of this package leaflet.
6. Don’t forget to spray the underside, neck and feet. To get to the underside of a dog, encourage it to roll over or sit. If your pet is a cat, you may need to lift it to get to the underside.
7. To ensure coverage of the head region, spray the product onto your glove and rub gently around the face of your pet, avoiding the eyes and ears.
8. When treating puppies, kittens or nervous cats, you may prefer to use a glove to apply the product all over.
9. When your pet has been thoroughly covered, massage the coat all over to make sure the spray gets right down to the skin. Let your pet dry naturally in a well ventilated area.
10. Keep your pet away from fires, heat or surfaces likely to be affected by the alcohol spray until dry and for at least 30 minutes after treatment.
11. Do not eat, drink or smoke when applying the spray. Do not use the product if you or your pet have a known hypersensitivity to insecticides or to alcohol. Wash hands after use.

10. **WITHDRAWAL PERIOD**

Not applicable.

11. **SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Shelf life after first opening the container: 6 months.

12. **SPECIAL WARNINGS**

Special warnings for each target species:

Treatment of bedding, carpets and soft furnishings with a suitable insecticide will aid reduction in environmental challenge and maximise the duration of protection against re-infestation provided by the product.

The product is not suitable for direct treatment of the environment.

For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the product. Bathing or shampooing up to four times in two months has been shown to have no significant effect on the residual efficacy of the product.

Monthly treatment is recommended when more frequent shampooing is carried out.

Special precautions for use in animals:

Do not exceed the recommended dosage.

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

Do not spray directly onto areas of broken skin.

Allow treated animals to dry in a well ventilated room.

Do not confine animals in an enclosed space or pet carrier until the coat is totally dry.

In the absence of specific tolerance and efficacy data, the product is not recommended for the treatment of species other than cats and dogs.

It is important to make sure that animals do not lick each other following treatment.

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

Keep treated animals away from fires or other sources of heat, and surfaces likely to be affected by the alcohol spray, for at least 30 minutes following spraying and until the fur is totally dry.

Do not spray on a naked flame or any incandescent material.

For external use only.

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.

People with known asthma or known hypersensitivity to insecticides or alcohol 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. If irritation occurs, seek medical advice. After accidental ocular exposure the eye should be rinsed carefully with plain water.

Treated animals should not be handled until the fur is dry, and children should not be allowed to play with treated animals until the fur 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.

Spray animals in the open air or a well ventilated room.

Do not breathe spray. Do not smoke, drink or eat during application.

Wear PVC or nitrile gloves during treatment of animals. It is recommended to wear a waterproof apron for the protection of clothing.

If clothing becomes heavily wetted with the product, it should be removed and washed before re-use.

Dispose of gloves after use and then wash hands with soap and water.

Treatment of multiple animals:

Good ventilation is particularly important where several animals are to be treated. Treat multiple animals outside, or reduce the build up of vapour by removing the animals from the treatment room while the alcohol is evaporating and ensure that the treatment room is well ventilated

between individual treatments. In addition, ensure that the drying room is well ventilated and avoid housing several recently treated animals within the same air space.

Other precautions

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

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

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. The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Month YYYY

15. OTHER INFORMATION

For animal treatment only.

Treatment of bedding, carpets and soft furnishings with a suitable insecticide will aid reduction in environmental challenge and maximise the duration of protection against re-infestation provided by the product. The alcohol carrier may have adverse effects on painted, varnished or other household surfaces or furnishings.

Package Information

100 ml high density polyethylene bottle fitted with a polypropylene, polyethylene, polyoxymethylene, low-density polyethylene (dip-tube), high density polyethylene and low density polyethylene pump sprayer capable of delivering 0.5 ml per spray.

250 ml and 500 ml high density polyethylene bottle fitted with a polypropylene, polyethylene, polyoxymethylene, low-density polyethylene (dip-tube), high density polyethylene and low density polyethylene pump sprayer capable of delivering 1.5 ml per spray.

Not all pack sizes may be marketed.

Local Representative:

To be completed nationally