

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **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]

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Each ml contains**

##### Active substance:

Fipronil 2.5 mg

##### Excipient:

For full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Cutaneous spray, solution.  
A clear, colourless solution

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs and cats

#### **4.2 Indications for use, specifying the target species**

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.

#### **4.3 Contraindications**

Do not use on sick (systemic diseases, fever...) or convalescent animals.

Do not use in rabbits, as adverse reactions and even death could occur.

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

#### 4.4 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.

#### 4.5 Special precautions for use

i. 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 (see also section 4.5 (ii)).

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.

ii. 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 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.

iii. 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.

Adverse reactions (frequency and seriousness)

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.

#### **4.7 Use during pregnancy, lactation or lay**

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.

The formulation is very well tolerated by puppies following treatment of the lactating bitch.

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

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.9 Amounts to be administered and administration route**

Route of administration: mechanical pump spray for external use.

Method of administration: Adjust the pump nozzle to spray setting. 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.

Posology: 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 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.

A Practical Guide To Treatment With The Product

The table below is a guide to the approximate number of pumps required for the treatment of cats and dogs.

	<b>Short hair Dogs and cats (Hair length &lt;2cm)</b>	<b>Medium Hair Dogs/ Long hair cats (Hair length 2-4cm)</b>	<b>Long Hair dogs and cats (Hair length &gt;4cm)</b>
<b>100 ml pack</b> (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
<b>250 ml pack</b> (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
<b>500 ml pack</b> (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

Properties: The formulation contains a coating agent. Therefore, spraying builds up a film and makes the fur glossy.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

Puppies and kittens from 2 days of age may be safely treated.

For optimal control of flea and/or tick infestation the treatment schedule should be based on the local epidemiological situation.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

The risk of experiencing adverse effects (see section 4.6) may increase when overdosing, so animals should always be treated with the correct dose according to bodyweight. Start an appropriate symptomatic treatment in case of overdosing.

#### **4.11 Withdrawal periods**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Ectoparasiticides for topical use, fipronil

ATCvet code: QP53AX15

#### **5.1 Pharmacodynamic properties**

Fipronil is a member of the phenylpyrazole family of broad spectrum, non-systemic, insecticides/acaricides, which acts by blocking the GABA receptor to kill the target parasite on contact.

#### **5.2 Pharmacokinetic properties**

+ Absorption

The amount of fipronil absorbed by the skin in the dog, after application of the spray to the coat and skin is extremely slight to negligible.

+ Distribution

The persistence of fipronil on the hair is very long (on average  $52.5 \pm 11.5$  days), given that the limit of quantification of the assay method is  $0.25 \mu\text{g/g}$ .

+ Biotransformation

In all species fipronil is mainly metabolised to its sulphone derivative (RM1602), which also possesses insecticidal and acaricidal properties.

The RM1602 detected on the hair after spray application in dogs may be explained by its presence in the original raw material.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Copovidone (K28)  
Isopropyl Alcohol  
Purified Water

#### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.  
Shelf life after first opening the immediate packaging: 6 months.

### **6.4 Special precautions for storage**

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

### **6.5 Nature and composition of immediate packaging**

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.

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

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.

## **7. MARKETING AUTHORISATION HOLDER**

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

## **8. MARKETING AUTHORISATION NUMBER**


Vm 02000/4384

**9. DATE OF FIRST AUTHORISATION**

September 2014

**10. DATE OF REVISION OF THE TEXT**

January 2016

 12 January 2016