# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flevox 2.5 mg/ml cutaneous spray, solution for cats and dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains

**Active substance:**
Fipronil 2.5 mg

**Excipients:**
For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Cutaneous spray, solution
Clear, colourless liquid.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cats and dogs.

### 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*).
The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).
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

Do not exceed the recommended dosage.
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.
For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.
When used as part of a strategy for the treatment of flea allergy dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended.
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

Special precautions for use in animals

Avoid contact with the animal's eyes. In the case of accidental eye contact immediately and thoroughly flush the eyes with water. If eye irritation persists, seek veterinary medical advice.
Do not spray directly onto areas of injured skin.
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 animals

This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided. After accidental ocular exposure the eye should be rinsed carefully with plain water.
Operators with a known hypersensitivity to the active substance or alcohol or with asthma should avoid contact with the product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and 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.
Wash splashes from skin with soap and water immediately. If irritation occurs, seek medical advice. People with known sensitivity or asthma may be particularly sensitive to the product. Do not use product if you have previously experienced a reaction to it.
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

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

## 4.6 Adverse reactions (frequency and seriousness)

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
Among the very rare suspected adverse reactions, transient cutaneous reactions erythema, pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

## 4.7 Use during pregnancy, lactation or lay

Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit.
The formulation is very well tolerated by puppies following treatment of the lactating bitch.
Data are not available on treatment of pregnant queens or nursing 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; with the pump delivering 0.5 ml (100 ml bottle) or 1.5 ml (250 ml bottle) or 3 ml (500 ml bottle) spray per pump.

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, or 1 to 2 pump application(s) of the 500 ml presentation.

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 500 ml pack contains approximately 4 treatments for a short haired large sized dog (40 kg).

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

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

## 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 period(s)

Not applicable.

# 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, fipronil
ATCvet code: QP53AX15

## 5.1 Pharmacodynamic properties

Fipronil exhibits insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp), ticks (*Rhipicephalus* spp., *Ixodes* spp.) and lice (*Trichodectes* spp. and *Felicola* spp.) in the dog and cat.

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. The product may aid in the control of a number of ectoparasite species in dogs and cats.The product is active against *Ixodes* spp. including *Ixodes ricinus*, important as the vector of Lyme disease.Treatment with the product has been shown to result in a significant reduction in the incidence of flea allergy dermatitis in both dogs and cats.

## 5.2 Pharmacokinetic particulars

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 ± 11.5 days), given that the limit of quantification of the assay method is 0.25 µg/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
Isopropyl alcohol
Purified water

## 6.2 Major incompatibilities

Not applicable.

### 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 1 year

### 6.4 Special precautions for storage

Store below 25°C.
Highly flammable.
Protect from direct sunlight.

### 6.5 Nature and composition of immediate packaging

Opaque, white 100 ml high density polyethylene bottle fitted with a low density polyethylene/polypropylene pump sprayer capable of delivering 0.5 ml per spray.
Opaque, white 250 ml high density polyethylene bottle fitted with a low density polyethylene/polypropylene pump sprayer capable of delivering 1.5 ml per spray.
Opaque, white 500 ml high density polyethylene bottle fitted with a low density polyethylene/ polypropylene pump sprayer capable of delivering 3.0 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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

## 7. MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

## 8. MARKETING AUTHORISATION NUMBER

Vm 01656/4058

## 9. DATE OF FIRST AUTHORISATION

07 January 2013

## 10. DATE OF REVISION OF THE TEXT

September 2017

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

Approved: 05 September 2017