# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPRON 134 mg spot-on solution for dogs M

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tube (1.34 ml) contains:
**Active substance:** Fipronil 134 mg
**Excipients:**
Butylhydroxyanisole (E 320) 0.268 mg
Butylhydroxytoluene (E 321) 0.134 mg

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Spot-on solution.

Clear, yellow to yellow-green solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species
Dogs.

### 4.2 Indications for use, specifying the target species
Treatment and prevention of flea infestation *(Ctenocephalides* spp.) and (*Rhipicephalus* spp., *Dermatocentor* spp., *Ixodes* spp.) in dogs.
Treatment and prevention related flea allergy dermatitis (FAD) in dogs.
Prevention and treatment of infestation by lice (*Trichodectes canis*) in dogs.

### 4.3 Contraindications
In respect of the absence of data do not apply to animals younger than 8 weeks and/or weighing less than 2 kg.
Do not apply to sick animals (systemic disease, fever) and convalescent animals.
Do not use in rabbits. It can cause a serious reaction or death.
The product is intended for dogs, do not apply to cats. Overdose can occur.
Use an appropriate size of container according to the actual weight of the dog.
Do not use in case of hypersensitivity to the active substances or to any of the excipients.

### 4.4 Special warnings for each target species
Avoid contact with animal's eyes.
With respect to a possible risk of parasite resistance to the active substance, and thus a reduced effect of therapy, the following rules of treatment with ectoparasiticides should be observed:
- Avoid too frequent and recurring use of ectoparasiticides of the same group
- Observe the determined dosage and dosing regimen. Administer the product in doses recommended by the manufacturer so as to ensure the optimal therapeutic effect.

### 4.5 Special precautions for use

**Special precautions for use in animals**

It is important to apply the product on such a place from which the animal cannot lick it and prevent mutual licking of animals after application. Apply the product to the skin surface only. Do not administer orally or parenterally. Avoid administration of the product on the mucous membranes (eyes, nostrils, genitals and injured skin).
In case of fleas, the other animals in the household should be treated with insecticides simultaneously.
Bathing/shampooing of the animal is not recommended within 2 days after application, as well as bathing more frequent than once a week.
After application prevent your dog from swimming in natural water sources (see section 6.6).
**Some ticks can attach after treatment, but they are killed 24-48 hours after application. This usually occurs before the tick size changes maximally, which minimizes, but does not exclude the risk of transmission of transmissible diseases.**
Fleas from pets often infest animal's crates, places where the animal sleeps and resting areas, such as carpets and soft furnishings which should be treated regularly with suitable insecticides and cleaned with a vacuum cleaner in case of massive infestation and at the beginning of protective measures.

**Special precautions to be taken by the person administering the veterinary medicinal product to animals**
People with a known hypersensitivity to fipronil or to any of the excipients should avoid contact with the product.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.
This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided.
In the case of accidental eye contact, immediately and thoroughly flush the eyes with water. In the case of accidental eye contact the eye should be rinsed carefully with plain water.
If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
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 should not be allowed to sleep with owners, especially children.
Do not smoke, drink or eat during application. Wash hands after use.

**Other precautions:**
Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.
The product may have adverse effects on painted, varnished or other household surfaces or furnishings.

**4.6 Adverse reactions (frequency and seriousness)**
Short-term hypersalivation due to the nature of vehicle may occur after licking.
Transient skin reactions at the injection site (hair discolouration and loss, itching, redness) and general pruritus or alopecia were reported very rarely after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperaesthesia, depression, nervousness), vomiting difficulty breathing were reported.
Cosmetic defects (bonded hair, white deposits) may occur at the injection site.
Avoid overdose.
In case of persisting adverse effects seek the advice of a veterinarian.

**4.7 Use during pregnancy and lactation**
Safety has been verified in breeding and pregnant dogs and in dogs in lactation, at which a triple dose than recommended was administrated several times.
The product can be applied to breeding, pregnant and lactating dogs.

**4.8 Interaction with other medicinal products and other forms of interaction**
None known.

### 4.9 Amounts to be administered and administration route

For lack of data the minimum time between two applications is 4 weeks.
Method of administration: spot-on use.

Dosage depends on the weight of animal.
Dogs weighing above 10 kg and to 20 kg: the contents of one tube of 1.34 ml (M)
This ensures a minimum recommended dose of fipronil of 6.7 mg/kg bw.

Monthly treatment is recommended in case of a high risk of repeated attacks by fleas, if the dog is allergic to flea bites, in case of necessary control of tick infestation, or at frequent bathing of the dog using hypoallergenic or moisturizing shampoos. In areas where there is no serious infestation by fleas and ticks, FIPRON spot-on for dogs can be applied every two to three months.

Method of administration:
Hold the tube with the neck upwards and knock the neck repeatedly with your finger. Break off the tip carefully by twisting motion. Part the hair of the animal in the withers in front of the shoulder blades until the skin is visible. Place the applicator tip on the skin and press the tube repeatedly to empty the entire contents of the tube directly on the skin.

FIPRON spot-on for dogs is effective against flea infestation for approximately two months and against ticks for up to 1 month, depending on the strength of environmental contamination. Fleas are killed within 24 hours after infestation.

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

Laboratory studies confirmed safety for the target species. Laboratory studies were performed on puppies (8 weeks old) and on dogs weighing about 2 kg. The administrative dose was five times higher than recommended dose. Studies showed no adverse effects. The risk of adverse effects (see section 4.6) may increase in case of overdose, therefore animals should be treated always right pipette size which is selected according to weight of animal.

### 4.11 Withdrawal periods

Not applicable.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other ectoparasiticides for topical use
ATCvet code: QP53AX15

### 5.1 Pharmacodynamic properties

Fipronil is a broad spectrum insecticide/acaricide derived from phenylpyrazole. It is toxic for arthropods after contact with the body surface or if ingested, and acts on adult and larval stages. In the insect CNS it interacts with receptors of gamma-aminobutyric acid (GABA), which regulate chloride channels. It blocks the transfer of chloride ions across cell membranes. This results in excessive nerve stimulation, uncoordinated activity of the nervous system and subsequent death of the insects and mites. Acaricidal effect is also caused by the destructive action on the salivary glands of ticks, which prevents sucking of the animal. Fipronil reproductive toxicity was found in female ticks (irreversible changes in the oocytes).

### 5.2 Pharmacokinetic properties

After product application the active substance penetrates the skin of the animal, spreads by concentration gradient from the application site to the periphery (lumbar area, groins, etc.), accumulates in the fat component of the skin and hair follicles, from which it is gradually released to the skin and coat. This ensures a long lasting activity. The concentration of fipronil on the hair gradually decreases, after 56

days the concentration measured on the hair was 3-4 µg/g. After topical administration, fipronil is absorbed in minimal amounts (up to 1%). In the body it is metabolised to its sulfone derivative that also has insecticidal and acaricidal effects.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients
Butylhydroxyanisole (E 320)
Butylhydroxytoluene (E 321)
Povidone K-16.5
Polysorbate 80
Ethanol 96%
Diethylene glycol monoethyl ether

### 6.2 Incompatibilities
Not applicable.

### 6.3 Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Use immediately after opening the bag.

### 6.4 Special precautions for storage
This veterinary medicinal product does not require any special temperature storage conditions.
Store in the original container in order to protect from light.
Store in a dry place.

### 6.5 Nature and composition of immediate packaging
Transparent single-dose PE tube with snap-off tip (PE). The tubes are placed individually in sealed sachets (PET/Al/PE). The sachets are then placed in a cardboard box.

Pack size: 1, 3 or 25 single-dose tubes

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 product
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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. Do not contaminate ponds, waterways or ditches with the product or empty containers.

## 7. MARKETING AUTHORISATION HOLDER
Bioveta, a. s.
Komenského 212
683 23 Ivanovice na Hané
Czech Republic

## 8. MARKETING AUTHORISATION NUMBER

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

## 10. DATE OF REVISION OF THE TEXT

**OTHER INFORMATION**