SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPRON 50 mg spot-on solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tube (0.5 ml) contains:
Active substance: Fipronil 50 mg
Excipients:
Butylhydroxyanisole (E320) 0.10 mg
Butylhydroxytoluene (E321) 0.05 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Pure yellow to yellow-green coloured solution.

4. CLINICAL PARTICULARS

4.1 Target species
Cats.

4.2 Indications for use, specifying the target species
Treatment and prevention of flea infestation *(Ctenocephalides felis)* and associated allergies to flea bite (FAD) in cats. Treatment and prevention of tick attack (*Ixodes* spp., *Rhipicephalus* spp.) and lice attack (*Felicola subrostratus*) in cats.

4.3 Contraindications
Due to the absence of available data, the product should not be administered to kittens less than 8 weeks old and/or weighing less than 1 kg.
Do not use in sick (systemic diseases, fever) or convalescent animals.
Do not use in rabbits. Adverse reactions and even death could occur.
Do not use in case of hypersensitivity to the active ingredient or any excipient of the product.

4.4 Special warnings for each target species
Avoid contact of the product with the eyes of the animal.
With regards to the risk of possible resistance of parasites to the active ingredient and thereby reduced effect of therapy, there should be the rules to handle ectoparasiticides observed:
- avoid too early and repeated use of ectoparasiticides from the same group
- follow the prescribed dosage and dosing regimen. Administer the product in doses recommended by the manufacturer so that the optimal therapeutic effect is achieved.

4.5 Special precautions for use

Special precautions for use in animals
It is necessary to ensure application of the preparation on such a place, from which the animal cannot lick it and prevent mutual licking among animals. The preparation should be applied only on the skin surface. Do not administer orally or parenterally. Avoid application of the product on mucosa (to the eyes, nostrils, on the mucosa of genitals and on the sites of injured skin).

In case of flea occurrence, simultaneous treatment of other animals in the household with ectoparasiticides is recommended.
Bathing / shampooing the animal during 2 days after application and bathing more frequent than once a week are not recommended.
Some ticks may attach after treatment, but they are killed in 24-48 hours after application. This usually happens before the maximum sucking of the tick, which minimizes, but does not eliminate the risk of transmitting transmissible diseases.
Pet fleas often infest the animal's carrier boxes, places, where the animal sleeps and rests, such as carpets and household equipment, which in case of massive infestation and at the beginning of the control measures should be treated with suitable insecticides and vacuumed.

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. Cats 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 severity)
If licking occurs, a brief period of hypersalivation may occur due to the nature of the carrier. Among the extremely rare adverse reactions after treatment, transient cutaneous reactions at the application site (alopecia, pruritus, erythema, creation of scales) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs) and vomiting have been observed.
Cosmetic defects may appear at the application site (hair glued together, white deposits).
Avoid overdose.
In case of persisting adverse effects seek help of a veterinary doctor.

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

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

4.9 Posology and method of administration
In the absence of data, the minimum interval between applications is 4 weeks.
Method of administration: spot on-use.

Dosage:
Apply 1 tube of 0.5 ml on the skin between shoulder blades.

Method of administration:
Hold the tube neck upright and tap the neck with your finger several times. Carefully break the tip with the twisting motion. Part the coat of the animal between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze the tube several times to empty the whole content of the tube directly onto the skin.

One dose provides protection against flea infestation for up to 5 weeks. The product protects against ticks for 3 to 4 weeks.
In the case of flea *Ctenocephalides felis* allergic dermatitis indication, repeated application of the product in 4-week intervals is recommended.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
Laboratory studies confirmed safety for the target species. Laboratory studies were performed on kittens (8 weeks old) and on cats weighing about 1 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 period(s)
Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other ectoparasiticides for local application
ATC vet code: QP53AX15

5.1 Pharmacodynamic properties
Fipronil is a broad-spectrum insecticid/acaricid derived from phenylpyrazole. It is toxic for arthropods after contact with the surface of ther body or after ingestion. It acts on both adults and larval stages. It interacts with gamma-aminobutyric acid (GABA) receptors in central nervous system of insect. These receptors regulate chloride channels. Fipronil thereby blocks transfer of chloride ions across the cell membranes. This results in excessive nervous stimulation, uncoordinated activity of the central nervous system and consequent death of insects and acarids. Acaricidal effect is also caused by the destructive action to the salivary glands of ticks, thereby preventing the suction on the animal. Reproductive toxicity of fipronil has been shown in female ticks (irreversible changes of oocytes).

5.2 Pharmacokinetic particulars
After an application of product to the animal the active ingredient is absorbed into the upper layers of the skin. It spreads by concentration gradient from the application site to peripheral parts (lumbar area, groins etc.), cumulates in the skin fat and in hair follicles, from where it is gradually released onto the skin and coat. This results in long lasting activity. Fipronil is not absorbed into the lower layers of the skin or into the subcutaneous tissue after the topical administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Butylhydroxyanisole (E 320)

Butylhydroxytoluene (E 321)
Povidone K -16.5
Polysorbate 80
Ethanol 96%
Diethylenglycol-monoethylether

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 sachet.

6.4 Special precautions for storage
This veterinary medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect the product 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.

Package sizes: 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 products
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