

1.3.1	Fypzyst 50 mg spot-on solution for cats
SPC, Labeling and Package Leaflet	CZ

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FYPRYST 50 mg spot-on solution for cats

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 pipette (0.50 ml) contains:

#### Active substance:

Fipronil 50 mg

#### Other ingredients:

Butylhydroxyanisol (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  
Light yellow liquid.

### 4. CLINICAL PARTICULARS

#### 4.1 Target species

Cats

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

The treatment and prevention of the infestation by fleas (*Ctenocephalides felis*) and ticks (*Rhipicephalus* spp., *Dermacentor* spp., *Ixodes* spp.) on cats.

Treatment and control of Flea Allergy Dermatitis (FAD) in cats.

Prevention and treatment of infestation with *Felicola subrostratus* biting lice on cats.

#### 4.3 Contraindications

In the absence of available data, the product should not be used on kittens less than 8 weeks old and/weighing less than 1 kg.

Do not use the product on sick animals (systemic disease, fever) or convalescent animals.

Do not use in rabbits due to a risk of adverse reactions or even death.

#### 4.4 Special warnings for each target species

Avoid contact of the product with the animal's eyes.

#### 4.5 Special precautions for use

##### i) Special precautions for use in animals

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Tick present at the animals should be removed prior to the use of the product to decrease the risk of transmissible diseases.

It is important to make sure that the product is applied to an area where the animal cannot lick it off, and to make sure that animals do not lick each other following treatment.

No data on the effect of bathing/shampooing on the efficacy of the product in cats are available.

However, based on information concerning the efficacy in dogs shampooed for two days after application of the product, it is not recommended to bath cats within two days after application of the product.

There may be an attachment of single ticks. For this reason, a transmission of infectious disease by ticks cannot be completely excluded if conditions are unfavourable. Ticks will be killed and fall of the host within 24 to 48 hours after infestation without having had a blood meal, as a rule. An attachment of single ticks after treatment cannot be excluded.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and home equipment which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

#### ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

The product can cause irritation of mucous membranes and eyes.

Therefore, avoid the contact of the product with the mouth and eyes.

People with known hypersensitivity to Fipronil or alcohol should avoid contact with the veterinary medicinal product. Be careful to prevent the contact of fingers with the contents. If the contact occurs, wash your hands with water and soap.

After accidental ocular exposure the eye should be rinsed carefully with plain water.

Wash your hands after the use.

Do not handle with the animals treated and prevent children from playing with them till the application site is dry. It is therefore recommended that animals are not treated during the day but during the early evening and the treated animals should not be allowed to sleep with their owners, particularly children.

Do not smoke, drink and eat in the course of the product application.

#### **4.6 Adverse reactions (frequency and seriousness)**

In the case of licking, a brief period of hypersalivation may be observed due mainly to the nature of the carrier. Among the extremely rare suspected adverse reactions, transient cutaneous reactions at the application site (scaling, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs) or vomiting have been observed after use.

Avoid the overdose.

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

The safety of the product was demonstrated in breeding, pregnant and lactating queens treated with multiple consecutive doses at up to three times the maximum recommended dose.

The product Fypryst spot-on solution can be used in breeding and pregnant and to lactating cats.

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

None known.

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

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

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Dosage:

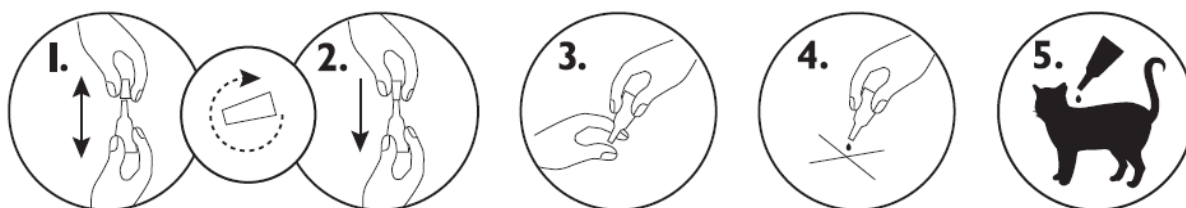
Apply contents of 1 unit-dose pipette of 0.5 ml onto the skin between shoulder blades.

Route of administration:

Spot-on use.

Method of administration:

Remove the unit-dose pipette from the triplex bag. Hold the unit-dose pipette in an upright position, twist and pull the cap off. Turn the cup around and place the other end of the cap back on the unit-dose pipette. Push and twist the cap to break the seal, then remove the cap from the unit-dose pipette. Part the coat of the animal between the shoulder blades until the skin is visible. Place the tip of the unit-dose pipette on the skin and squeeze the unit-dose pipette several times to empty its contents onto the skin.



One dose of the product is effective against fleas infestation for up to 5 weeks.  
The product is effective against ticks for 2 weeks.

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

Laboratory studies supporting the product safety in the target species of animals implemented in cats and kitten aged 8 weeks and older and weighing about 1kg treated once a month at five times the recommended dose for six consecutive months, demonstrated no undesirable effects.

The risk of experiencing adverse effects may however increase with overdosing (see section 4.6). Itching may occur following the treatment.

Overdose application of the product will cause a sticky appearance of hairs at the treatment spot. However, should this occurs, it will disappear within 24 hours post application.

**4.11 Withdrawal period(s)**

Not applicable.

**5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Ectoparasiticides for topical use  
ATCvet code: QP53AX15

**5.1 Pharmacodynamic properties**

Fipronil is an insecticide/acaricide in the phenylpyrazole family. It acts on arthropods by the interaction with ligands of chloride channels, particularly with those that are regulated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking the pre- and post-synaptic transfer of chloride ions across the cellular membranes. This results in uncontrolled activity of the central nervous system and death in insects and acarids.

The product Fypryst spot-on solution comprises the active ingredient fipronil, which possesses a unique mechanism of the action on fleas and ticks. Fypryst spot-on solution is accumulated in the lipidic component of the skin and hair follicles and it is continuously eliminated from the hair follicles onto the skin and hairs, thus providing a long term persistent activity.

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## 5.2 Pharmacokinetic particulars

The total amount of fipronil absorbed through the skin after local application of the product Fypryst spot-on solution is negligible.

After the application of the product Fypryst spot-on solution, a concentration gradient of fipronil is set up on the fur of the animal extending from the point of application to the peripheral areas (lumbar zones, flanks,...) Fipronil is not absorbed and thus it is not metabolized in the organism.

The concentration of fipronil on the hair decreases with time to achieve a level of 1 µg/g two months after the administration.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Butylhydroxytoluene (E321)  
 Butylhydroxyanisol (E320)  
 Ethanol (96%)  
 Polysorbate 80  
 Povidone K25  
 Diethylene glycol-monoethylether

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

### 6.4. Special precautions for storage

Store in the original package in order to protect from light.

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

### 6.5 Nature and composition of immediate packaging

Pipette (PP), closure with spike (PE or POM): unit-dose pipettes of 0.50 ml spot-on solution in a triplex bag (PETP/Al/LDPE).

Box of 1, 3, 6, 10, 20 pipettes.

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.

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

## 7. MARKETING AUTHORISATION HOLDER

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

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**8.      MARKETING AUTHORISATION NUMBER(S)**

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

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