

1.3.1	FYPRYST 67 mg spot-on solution for dogs
SPC, Labeling and Package Leaflet	CZ

**PACKAGE LEAFLET FOR:**

**FYPRYST 67 mg spot-on solution for dogs**  
**FYPRYST 134 mg spot-on solution for dogs**  
**FYPRYST 268 mg spot-on solution for dogs**  
**FYPRYST 402 mg spot-on solution for dogs**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:  
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FYPRYST 67 mg spot-on solution for dogs  
FYPRYST 134 mg spot-on solution for dogs  
FYPRYST 268 mg spot-on solution for dogs  
FYPRYST 402 mg spot-on solution for dogs  
Fipronil

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

1 pipette (0.67 ml) contains:

**Active substance:**

Fipronil 67 mg

**Excipients:**

Butylhydroxyanisol (E320)	0.134 mg
Butylhydroxytoluene (E321)	0.067 mg

1 pipette (1.34 ml) contains:

**Active substance:**

Fipronil 134 mg

**Excipients:**

Butylhydroxyanisol (E320)	0.27 mg
Butylhydroxytoluene (E320)	0.13 mg

1 pipette (2.68 ml) contains:

**Active substance:**

Fipronil 268 mg

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**Excipients:**

Butylhydroxyanisol (E320)	0.54 mg
Butylhydroxytoluene (E321)	0.27 mg

1 pipette (4.02 ml) contains:

**Active substance:**

Fipronil 402 mg

**Excipients:**

Butylhydroxyanisol (E320)	0.80 mg
Butylhydroxytoluene (E321)	0.40 mg

**4. INDICATION(S)**

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

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

Prevention and treatment of infestation with *Trichodectes canis* biting lice on dogs.

**5. CONTRAINDICATIONS**

In the absence of available data, the product should not be used on puppies less than 8 weeks old and/or weighing less than 2 kg.

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

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

The product is intended for use in dogs. Do not use it in cats, as this could lead to overdosing.

**6. ADVERSE REACTIONS**

If licking occur, 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 (skin discoloration, local alopecia, pruritus, erythema) and general 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.

Avoid the overdose.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

**7. TARGET SPECIES**

Dogs

**8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

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Dosage:

One unit-dose pipette of 0.67 ml spot-on solution per dog weighing over 2 kg and up to 10 kg bodyweight.

One unit-dose pipette of 1.34 ml spot-on solution per dog weighing over 10 kg and up to 20 kg bodyweight.

One unit-dose pipette of 2.68 ml spot-on solution per dog weighing over 20 kg and up to 40 kg bodyweight.

One unit-dose pipette of 4.02 ml spot-on solution per dog weighing over 40 kg bodyweight. One unit-dose pipette of 4.02 ml spot-on solution and an appropriate smaller unit-dose pipette per dog weighing over 60 kg.

In this way, you will provide the minimum recommended fipronil dose of 6.7 mg/kg.

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

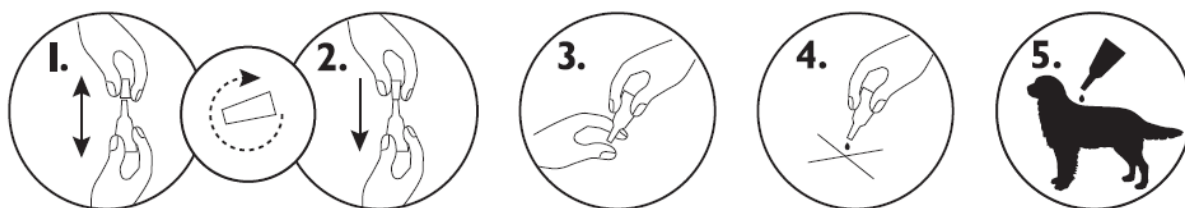
Monthly treatment is recommended in the case of a high risk of the repeated infestation with fleas, if the dog is allergic to flea biting, and in the case of necessary control of the infestation with ticks or of frequent bathing of the dog with the use of hypoallergenic or softening shampoos. In areas where there is no serious danger of the infestation with fleas and ticks, the product Fypryst spot-on solution may be applied every second to third month.

Administration route:

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. Spread the animal hairs in the area of the crest before blade bones to make the skin visible. Put the tip of the unit-dose pipette onto the skin and press the unit-dose pipette several times to empty its contents directly onto the skin at one site.



The product has persistent efficacy against flea infestation for two months and against ticks for up to 4 weeks, depending on the strength of environmental contamination. Fleas are killed within 24 hours after infestation.

## 9. ADVICE ON CORRECT ADMINISTRATION

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

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.

Bathing/immersion in water within 2 days after application of the product and more frequent bathing than once a week should be avoided, as no study has been performed to investigate how this affects the efficacy of the product. Emollient shampoos can be used prior to treatment, but reduce the duration

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of protection against fleas to approximately 5 weeks when used weekly after application of the product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect against fleas during a 6 week long study.

Dogs should not be allowed to swim in watercourses for 2 days after application (See section 13).

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 cannot be excluded during the period of efficacy of the product.

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

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

## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

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

Do not use this veterinary medicinal product after the expiry date which is stated on the packaging after {EXP}.

## 12. SPECIAL WARNING(S)

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.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

#### 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

#### 15. OTHER INFORMATION

One printed carton contains unit-dose pipettes of 0.67 ml of the solution, each packed into triplex bag.  
 One printed carton contains unit-dose pipettes of 1.34 ml of the solution, each packed into triplex bag.  
 One printed carton contains unit-dose pipettes of 2.68 ml of the solution, each packed into triplex bag.  
 One printed carton contains unit-dose pipettes of 4.02 ml of the solution, each packed into triplex bag.  
 Box of 1, 3, 6, 10, 20 pipettes.  
 Not all pack sizes may be marketed.

Pharmacotherapeutic group: Ectoparasiticides for topical use, ATC Vet Code: QP53AX15

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 action on fleas and ticks. Fypryst spot-on solution is accumulated in the lipidic component of the skin and hair follicles and it's continuously eliminated from the hair follicles onto the skin and hairs, thus providing a long term persistent activity.

After topical application of the product Fypryst spot-on solution in dogs, absorption of fipronil through the skin is slight (approx. 15%). Variable concentrations of fipronil in the blood plasma were observed in dogs. 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,...). In dogs, fipronil is mainly metabolized to its sulphone (RM 1602), which also exerts insecticide and acaricide effects.

In dogs, the concentrations of fipronil on the hairs decrease with time to attain a level of approximately 3 - 4 µg/g 56 days after treatment.