

1.3.1	FYPRYST 268 mg spot-on solution for dogs
SPC, Labeling and Package Leaflet	CZ

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FYPRYST 268 mg spot-on solution for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 pipette (2.68 ml) contains:

Active substance:

Fipronil 268 mg

Excipients:

Butylhydroxyanisol (E320) 0.54 mg

Butylhydroxytoluene (E321) 0.27 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

Dogs

4.2 Indications for use, specifying the target species

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.

4.3 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 diseases, 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.

4.4 Special warnings for each target species

Avoid the 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.

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 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 6.6).

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.

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 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)

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.

4.7 Use during pregnancy, lactation or lay

The safety of the product was demonstrated in breeding and pregnant and in lactating bitches, treated with multiple consecutive doses at up to 3 times the maximum recommended dose.

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

4.8 Interaction with other medicinal products and other forms of interaction

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None known.

4.9 Amounts to be administered and administration route

Dosage:

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

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.

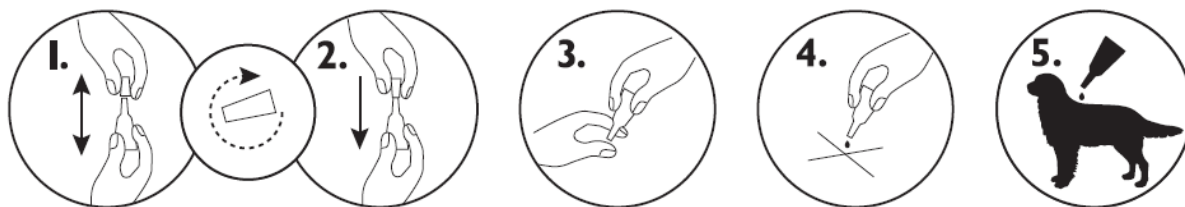
Monthly treatment is recommended in the case of a high risk of the repeated infestation with fleas, if the dog is allergic to flea biting, and in the case of necessary control of the infestation with ticks or of frequent bathing of the dog with the use of hypoallergenic or softening shampoos. In areas 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 is effective against flea infestation for two months and against ticks for up to 4 weeks, depending on the level of challenge due to pressure from environment. Fleas are killed within 24 hours after infestation.

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

No adverse effects were demonstrated in the laboratory studies supporting the product safety in the target species of animals carried out in 8 week-old puppies, growing dogs and weighing of about of 2 kg treated once at five times the recommended dose. The risk of experiencing adverse effects (see section 4.6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

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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 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.

5.2 Pharmacokinetic particulars

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.

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.

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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 2.68 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 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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

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