PACKAGE LEAFLET FOR:

FYPRYST 50 mg spot-on solution for cats

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 50 mg spot-on solution for cats
Fipronil

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

1 pipette (0.50 ml) contains:

Active substance:
Fipronil 50 mg

Other ingredients:
Butylhydroxyanisol (E320) 0.10 mg
Butylhydroxytoluene (E321) 0.05 mg

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

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.

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

7. TARGET SPECIES

Cats

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

Amounts to be administered:
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 will provide the protection against fleas infestation for up to 5 weeks.
The product is effective against ticks for 2 weeks.
Due to the absence of trials concerning the safety of the product, the minimum interval between applications is of 4 weeks.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid contact of the product with the animal's eyes.
It is important to provide the application of the product 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. Therefore, the removal of ticks already on the cat at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

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

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.

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 0.50 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 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 persistent activity.
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.