

FIPRON 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:
Bioveta, a.s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPRON 50 mg spot-on solution for cats
Fipronil

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 tube (0.5 ml) contains:

Active substance: Fipronil	50 mg
Excipients:	
Butylhydroxyanisole (E320)	0.10 mg
Butylhydroxytoluene (E321)	0.05 mg

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

4. INDICATIONS

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.

5. 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.

6. ADVERSE REACTIONS

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.

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 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton. Use immediately after opening the sachet.

12. SPECIAL WARNINGS

Special precautions for use in animals

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

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 ectoparasitocides 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 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.

Pregnancy and lactation:

Safety has been verified in breeding and pregnant cats and in cats in lactation, at which a triple dose than recommended was administratively several times.

The product can be applied to breeding, pregnant and lactating cats.

Interactions with other medicinal products and other forms of interaction: None known.

Overdose (symptoms, emergency procedures, antidotes): 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 6) may increase in case of overdose, therefore animals should be treated always right pipette size which is selected according to weight of animal.

Special precautions:

Due to the possibility of contamination with fleas in the site where is the animal moving it is necessary to decontaminate the environment regularly with an appropriate insecticide.

With regards to the risk of possible resistance to the active ingredient and thereby reduced effect of therapy, there should be the rules to handle ectoparasitocides observed:

- Avoid too early and repeated use of ectoparasitocides 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.

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 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2017.

15. OTHER INFORMATION

Package sizes: 1, 3 or 25 single-dose tubes.

Not all of the package sizes may be available on the market.

For animal treatment only.



Dimensions (mm):

Colours:

Prepared by:

Date:

A6 (105 × 148 mm) duplex printing

black

Musilová

23. 10. 2017

Approved by:

Date: