

PACKAGE LEAFLET

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FIPRON 134 mg spot-on solution for dogs M

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

Marketing Authorisation Holder and Manufacturer:

Bioveta, a. s.
Komenského 212
683 23 Ivanovice na Hané
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPRON 134 mg spot-on solution for dogs M
Fipronil

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 tube (1.34 ml) contains:

Active substance: Fipronil 134 mg

Excipients:

Butylated hydroxyanisole (E 320) 0.268 mg

Butylated hydroxytoluene (E 321) 0.134 mg

Clear, yellow to yellow-green spot-on solution.

4. INDICATIONS

Treatment and prevention of flea infestation (*Ctenocephalides* spp.) and (*Rhipicephalus* spp., *Dermatocentor* spp., *Ixodes* spp.) in dogs.

Treatment and prevention related flea allergy dermatitis (FAD) in dogs.

Prevention and treatment of infestation by lice (*Trichodectes canis*) in dogs.

5. CONTRAINDICATIONS

In respect of the absence of data do not apply to animals younger than 8 weeks and/or weighing less than 2 kg.

Do not apply to sick animals (systemic disease, fever) and convalescent animals.

Do not use in rabbits. It can cause a serious reaction to death.

The product is intended for dogs, do not apply to cats. Overdose can occur.

Use an appropriate size of container according to the actual weight of the dog.

Do not use in case of hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

Short-term hypersalivation due to the nature of vehicle may occur after licking. Transient skin reactions at the injection site (hair discolouration and loss, itching, redness) and general pruritus or alopecia were reported very rarely after use. Exceptionally, hypersalivation, reversible

neurologic symptoms (hyperaesthesia, depression, nervousness), vomiting difficulty breathing were reported.

Cosmetic defects (bonded hair, white deposits) may occur at the injection site.

Avoid overdose.

In case of persisting adverse effects seek the advice of a veterinarian.

If you notice any serious adverse effects or other reactions not listed in this leaflet, please inform your veterinary doctor.

7. TARGET SPECIES

Dogs.

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

For lack of data the minimum time between two applications is 4 weeks.

Method of administration: Spot-on use.

Dosage:

Dogs weighing above 10 kg and to 20 kg: the contents of one tube of 1.34 ml (M)

This ensures a minimum recommended dose of fipronil of 6.7 mg/kg bw.

Method of administration:

Hold the tube with the neck upwards and knock the neck repeatedly with your finger. Break off the tip carefully by twisting motion. Part the hair of the animal in the withers in front of the shoulder blades until the skin is visible. Place the applicator tip on the skin and press the tube repeatedly to empty the entire contents of the tube directly on the skin.

9. ADVICE ON CORRECT ADMINISTRATION

Monthly treatment is recommended in case of a high risk of repeated attacks by fleas, if the dog is allergic to flea bites, in case of necessary control of tick infestation, or at frequent bathing of the dog using hypoallergenic or moisturizing shampoos. In areas where there is no serious infestation by fleas and ticks, FIPRON spot-on for dogs can be applied every two to three months.

FIPRON spot-on for dogs is effective against flea infestation for approximately two months and against ticks for up to 1 month, depending on the strength of environmental contamination. Fleas are killed within 24 hours after infestation.

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 container in order to protect from light.

Store in a dry place.

Do not use after expiry date stated on the packaging.

Use immediately after opening the bag.

12. SPECIAL WARNINGS

Special precautions for use in animals

Avoid contact with animal's eyes.

It is important to apply the product on such a place from which the animal cannot lick it and prevent mutual licking of animals after application. Apply the product to the skin surface only. Do not administer orally or parenterally. Avoid administration of the product on the mucous membranes (eyes, nostrils, genitals and injured skin).

In case of fleas, the other animals in the household should be treated with insecticides simultaneously. Bathing/shampooing of the animal is not recommended within 2 days after application, as well as bathing more frequent than once a week.

After application prevent your dog from swimming in natural water sources.

Some ticks can attach after treatment, but they are killed 24-48 hours after application. This usually occurs before the tick size changes maximally, which minimizes, but does not exclude the risk of transmission of transmissible diseases.

Fleas from pets often infest animal's crates, places where the animal sleeps and resting areas, such as carpets and soft furnishings which should be treated regularly with suitable insecticides and cleaned with a vacuum cleaner in case of massive infestation and at the beginning of protective measures.

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, immediately and thoroughly flush the eyes with water. 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. Dogs 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 dogs and in dogs in lactation, at which a triple dose than recommended was administrated several times.

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

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 puppies (8 weeks old) and on dogs weighing about 2 kg. The administrative dose was five times higher than recommended dose. Studies showed no adverse effects. The risk of adverse effects (see section 4.6) may increase in case of overdose, therefore animals should be treated always right pipette size which is selected according to weight of animal.

Special warnings:

With respect to a potential flea infestation of the living place of animals, it is necessary to sanitize periodically the environment with a suitable insecticide.

With respect to a possible risk of parasite resistance to the active substance, and thus a reduced effect of therapy, the following rules of treatment with ectoparasiticides should be observed:

- Avoid too frequent and recurring use of ectoparasiticides of the same group
- Observe the determined dosage and dosing regimen. Administer the product in doses recommended by the manufacturer so as to ensure the optimal therapeutic effect.

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**15. OTHER INFORMATION**

Pack size: 1, 3 or 25 single-dose tubes

Not all pack sizes may be marketed.

For animal treatment only.