

FIPRON 268 mg spot-on solution for dogs L**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 268 mg spot-on solution for dogs L
Fipronil

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

1 tube (2.68 ml) contains:

Active substance:	268 mg
Fipronil	
Excipients:	
Butylated hydroxyanisole (E 320)	0.536 mg
Butylated hydroxytoluene (E 321)	0.268 mg

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

4. INDICATIONS

Treatment and prevention of flea infestation (*Ctenocephalides* spp.) and related flea allergy dermatitis (FAD) in dogs. Treatment and prevention of infestation by ticks (*Rhipicephalus* spp., *Dermatocentor* spp., *Ixodes* spp.) and 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 discoloration 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(S)
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 20 and to 40 kg: the contents of one tube of 2.68 ml (L) 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 intended for food-producing animals.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the 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 WARNING(S)

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 or animals with known hypersensitivity to insecticides or alcohol should avoid contact with the product.

People with epilepsy should handle the product with caution.

The product may cause irritation of eyes and mucous membranes. Therefore, use appropriate protective equipment and avoid contact with eyes, mucous membranes and mouth.

If the product gets into the eye, flush the eye carefully with clean water. In case of serious irritation seek medical attention.

This product may cause skin irritation.

Do not handle treated animals and do not allow children to play with them until the applied product has dried. It is therefore recommended not to treat animals during the day, but early in the evening, and not to allow the recently treated animals to sleep with their owners, especially children.

After application wash your hands with soap and water. Remove contaminated clothing which is in direct contact with the skin.

Take care to avoid finger contact with the content. If this occurs, wash your hands with water and soap.

In case of accidental ingestion seek medical advice immediately and show the package leaflet or label to a practitioner.

Note to physician: After ingestion of a large quantity of the product the following toxicity manifestations can be expected: nausea, vomiting, headache, dizziness, abdominal pain, sweating, restlessness, weakness and tonic-clonic convulsions.

The states are transient and usually resolve spontaneously. Excitation of epilepsy can occur in susceptible individuals, or at higher doses. Activated charcoal should be administered in the first step. There is no known specific antidote. Further treatment is symptomatic.

Do not smoke, drink or eat during application.

Fipronil may adversely affect aquatic organisms. After application prevent your dog from swimming in natural water sources for 2 days.

**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.

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, rivers or reservoirs with the product or empty containers. Medicines should not be disposed of via wastewater or household waste.

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

June 2012

15. OTHER INFORMATION**Use during pregnancy and lactation**

No studies on the administration of this product to pregnant and lactating bitches are available, therefore use the product only after assessment of the benefit/risk ratio by a veterinarian.

Interactions:

Fipronil and amitraz have a synergic effect.

Overdose:

Do not give the animals more than the recommended dose. The risk of adverse effects (see section 6) may increase in case of overdose.

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.

For animal treatment only.

The veterinary medicinal product is available without prescription.

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

Not all pack sizes may be marketed.



Dimensions (mm):

Colours:

Prepared by:

Date:

2 × A6

black

Vlková

27. 3. 2013

Approved by:

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Date:

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