beaphar

FIPROtec[®]

268mg Spot-On Solution for Large Dogs Fipronil

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE: Marketing outboringing holder

Marketing authorisation holder:

Beaphar B.V., Drostenkamp 3, 8101 BX, Raalte, The Netherlands T: +31 572 348 834, F: +31 572 348 835, E: hqb@beaphar.com

<u>Manufacturer responsible for batch release</u>: Beaphar B.V., Oude Linderteseweg 9, 8102 EV Raalte, Netherlands T: +31 572 348 834, F: +31 572 348 835, E: hqb@beaphar.com

ACTIVE SUBSTANCE AND OTHER INGREDIENTS:

1 pipette of 2.68 ml contains:	
Active substance:	
Fipronil	268.0 mg
Excipients:	
Butylhydroxyanisole (E-320)	0.536 mg
Butylhydroxytoluene (E-321)	0.268 mg
Benzyl alcohol (E-1519)	763.800 mg
Clear colourless to slightly yellow solution.	



WHAT DOES THIS PRODUCT DO?

Beaphar FIPROtec[•] **Spot-On for Large Dogs** kills fleas for up to 5 weeks and kills ticks from one week after application until four weeks after application.

WHAT'S IN THIS PRODUCT?

Each pipette contains 268mg Fipronil (active ingredient), 0.536mg butylhydroxyanisole (E320), 0.268mg butylhydroxytoluene (E321) and 763.800mg benzyl alcohol (E1519).

IS THIS PRODUCT SUITABLE FOR MY DOG?

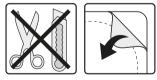
It is suitable for dogs from 8 weeks of age, and weighing 20–40kg. Do not use if your dog is sick or is recovering from an illness. Do not use on pregnant or nursing bitches. Ensure treated dogs do not come into contact with puppies under 8 weeks of age. Do not use if your dog is allergic to any of the ingredients. For external use only. Do not use on cats.

Do not use on rabbits as serious reactions, including death, can occur.

HOW DO I USE THIS PRODUCT?

Before every use, read the information on the inside of the box for full instructions and all warnings, including user warnings. Use the easy-peel corners to remove a pipette from its blister.

Do not puncture the foil with scissors, knives or other sharp instruments, as this may damage the pipette inside.



Holding the pipette upright, tap the neck section to ensure the contents fall back into the body of the pipette. Snip off the top of the pipette, part the fur between your dog's shoulder blades, place the tip of the pipette on the skin and apply the contents of one pipette to the skin surface. Apply half the pipette between the shoulder blades and half at the base of the head. For continuous flea protection, re-apply the product once every 4 weeks, but not more often.



HOW SHOULD I STORE AND DISPOSE OF THIS PRODUCT?

Keep the pipettes in the box, in order to protect from light, until ready to use them. Do not store above 25°C. Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with product or empty pipettes. The product may have adverse effects on painted, varnished or other household surfaces or furnishings. Dispose of empty pipettes immediately after use in the household rubbish.

WHAT DO I NEED TO KNOW TO TREAT MY DOG SAFELY?

Do not use simultaneously with other flea control products which are applied directly to the animal. Weigh your dog carefully before treating to ensure the product is safe to use. For external use only. Avoid contact with animal's eyes. In case of accidental eye contact, immediately and thoroughly flush the eyes with water. Do not apply to wounds or damaged skin. Avoid excessive wetting of the fur. I stickiness occurs, this will disappear within 24 hours. Apply the product in a position where your dog cannot lick it off. In a multi-pet household, ensure treated animals cannot groom each other following treatment and that all animals are treated with a suitable insecticide. Avoid frequent swimming or shampooing. Dogs should not be allowed to swim in watercourses for 2 days following treatment. Fleas from pets often infest the animal's bedding, basket and regular resting areas, such as carpets and soft furnishings, which should be treated with a household insecticide and vacuumed regularly.

POSSIBLE ADVERSE REACTIONS:

If licked off, the liquid may cause a brief period of excessive drooling due to the taste of the solvent. Very rarely, temporary skin discolouration, hair loss or itching can occur at the site of treatment. In a few cases, skin sensitivity may be severe. Very rarely, a dog may temporarily appear depressed, vomit or show changes in breathing. The risk of adverse reactions to the product may increase if overdosed. If you notice any effects after treatment, contact your veterinary surgeon.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- -Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If a tick attaches to your dog, there is a possibility of a transmission of infectious diseases from the tick to your dog.

USER WARNINGS: WHAT PRECAUTIONS SHOULD I TAKE TO PROTECT MYSELF AND FAMILY?

For animal treatment only. Keep out of the sight and reach of children. Keep pipettes in this pack until you are ready to use. This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided. In case of accidental eye contact, rinse the eye carefully with plain water. If eye irritation continues, seek medical advice and show this pack to the doctor. If you have a known allergy to Fipronil or any of the other ingredients, avoid contact with this product. Avoid contents coming into contact with the fingers. If this occurs, wash your hands with soap & water. Do not smoke, drink or eat during application. Wash hands after use. Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. Children should not be allowed to play with treated animals, which should not be handled until after 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.

Date label text last approved: February 2022

OTHER INFORMATION

1, 2, 3, 4, 6 pipettes are packed in a cardboard box. Not all pack sizes may be marketed.