SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 402 mg Spot on Solution for Extra Large Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 pipette of 4.02 ml contains:

Active substance:
Fipronil .....402.0 mg

Excipients:
Butylhydroxyanisole (E320) .....0.804 mg
Butylhydroxytoluene (E321).....0.402 mg
Benzyl alcohol (E1519) .....1145.700 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution
Clear colourless to slightly yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.
This product is suitable for dogs weighing 40 – 60 kg.

4.2 Indications for use, specifying the target species

The treatment and prevention of flea infestations (*Ctenocephalides felis*) in dogs. The duration of protection against flea infestations is 5 weeks.

The product protects against new tick infestations (*Dermacentor reticulatus, Rhipicephalus sanguineus*) in dogs from day 7 to day 28 after application of the product.

4.3 Contraindications

Do not use on dogs less than 8 weeks old and/or weighing less than 2 kg.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use on sick (e.g. systemic disease, fever) or convalescent animals.
Do not use in rabbits, as adverse reactions and even death could occur.

Do not use in cats, as this could lead to overdosing.

4.4 Special warnings for each target species

For optimal control of flea infestations in multi-pet households, all animals in the household should be treated with a suitable insecticide.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestations and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

No data on the effect of bathing/shampooing on the efficacy in dogs are available. Shampooing prior to or frequently after treatment may reduce product efficacy (see also section 6.6).

The product does not prevent ticks from attaching to the animal. In addition, efficacy against existing tick infestations has not been demonstrated. For this reason, transmission of infectious diseases cannot be excluded.

It is known that the product will protect against new tick infestations from day 7 to day 28 after application of the product. However, it is not known whether efficacy against new tick infestations persists beyond 4 weeks. Therefore, there may be gaps in protection from such infestations after subsequent re-applications of the product, even if the product is re-applied at the minimum interval of 4 weeks.

4.5 Special precautions for use

Special precautions for use in animals
For external use only. Do not apply the product on wounds or damaged skin.
Avoid contact with the animal’s eyes. In case of accidental eye contact immediately and thoroughly flush the eyes with water.

Animals should be weighed accurately prior to treatment (see section 4.3).

It is important to make sure that the product is applied to an area where the animal cannot lick it off, and to make sure that animals do not lick each other following treatment.

The potential toxicity of the product for puppies less than 8 weeks of age in contact with a treated bitch is not documented. Use according to a benefit/risk assessment by the responsible veterinarian

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Keep pipettes in original packaging until ready for use and dispose of used pipettes immediately.

Persons with known hypersensitivity to fipronil or to any of the excipients (see section 6.1) 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 of the product with mouth and eyes should be avoided.
After accidental ocular exposure the eye should be rinsed carefully with plain water.
Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the doctor.
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 watercourses for 2 days after application.
The product may have adverse effects on painted, varnished or other household surfaces or furnishings.

4.6 Adverse reactions (frequency and seriousness)

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

Suspected adverse reactions such as transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported very rarely after use. Hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed very rarely after use.

Do not overdose. The risk of adverse effects may increase in cases of overdose.
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).

4.7 Use during pregnancy, lactation or lay

Laboratory studies using fipronil have not produced any evidence of teratogenic or fetotoxic effects.
The safety of the product has not been established in pregnant or lactating bitches use only according to the benefit/risk assessment by the responsible veterinarian. If animals are treated during the lactating period, see section 4.5 (i).

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with other flea products which are applied directly onto the animal.

4.9 Amounts to be administered and administration route

Make sure you use the correct product, corresponding to the bodyweight of your dog.

Route of administration – By topical application to the skin. For external use only.

Dosage:

- 1 pipette of 4.02 ml per dog weighing over 40kg and up to 60 kg bodyweight
  The dosing rate is 6.7 – 10.05 mg fipronil per kg bodyweight.
- 2 pipettes of 2.68 ml (Fiprotec 268 mg spot-on for Large Dogs) per dog weighing over 60 kg bodyweight
  The dosing rate is up to 8.9 mg fipronil per kg bodyweight.

Method of administration – 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.

Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Cut off the top of the pipette with scissors.
Part the coat between the shoulder blades and at the base of the head until the skin is visible. Place the tip of the pipette on the skin and gently apply half of its contents onto the skin at both application sites.

Avoid applying the solution onto the fur and do not rub into the skin.
Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will usually disappear within 24-48 hours post application.

In the absence of safety studies, the minimum treatment interval is four weeks.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse effects have been demonstrated in the tolerance studies carried out with 8-week-old puppies, growing dogs and dogs weighing about 2 kg treated once at five times the recommended dose. The risk of causing side effects may however increase with overdosing. It is therefore recommended to always treat animals with the appropriate pipette size.

4.11 Withdrawal period

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides
ATCvet code: QP53AX15

5.1 Pharmacodynamic properties

Fipronil is an insecticide/acaricide in the phenylpyrazole family. It acts by inhibiting the GABA complex, binding to the chloride channel and thereby blocking pre- and post-synaptic transfer of chloride ions across the membrane. This results in uncontrolled activity of the central nervous system and death in insects and acarids.

5.2 Pharmacokinetic particulars

After topical application of the product on the dog, absorption of fipronil through the skin is slight. Low levels of fipronil may be detected in the plasma, with a very high variability between individuals.
After topical application, the product will spread from the site of treatment to cover the entire surface of the animal. 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 mainly metabolised to its sulfone derivative (RM1602), which also possesses insecticidal and acaricidal properties.

The concentrations of fipronil on the hair decrease with time.

5.3 Environmental warnings

The product may adversely affect aquatic organisms.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
Butylhydroxytoluene (E321)
Benzyl alcohol (E1519)
Diethylene glycol monoethyl ether

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Do not store above 25°C.

Keep pipette within blister and box until ready for use, in order to protect from light.

6.5 Nature and composition of immediate packaging

A blue pipette is composed of a heat-formed shell (polypropylene and acrylonitrile methyl acrylate copolymer/cyclic olefin copolymer polypropylene/polypropylene) and a film (acrylonitrile methyl acrylate copolymer/aluminium/polyester).

1, 2, 3, 6 pipettes are packed in a cardboard box.

Or

A blue pipette is composed of a heat-formed shell (polypropylene/cyclic olefin copolymer/ethylene-vinyl alcohol copolymer/polypropylene) and a film (polyethylene terephthalate/aluminium/polypropylene).

The blue pipette is enclosed in an aluminium blister (polyethylene /polyamide /aluminium / polyamide/polyethylene and polyamide/aluminium/polyethylene).

1, 2, 3, 4, 6 pipettes are packed in a cardboard box.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
The product may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

7. MARKETING AUTHORISATION HOLDER

Beaphar B.V.
Drostenkamp 3
8101 BX Raalte
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 41941/4004

9. DATE OF FIRST AUTHORISATION

08 August 2014

10. DATE OF REVISION OF THE TEXT

August 2019

Approved: 08 August 2019