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

Each pipette of 4.02 ml contains:
Active substance: Fipronil 402.0 mg
Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylhydroxyanisole (E320)	0.804 mg
Butylhydroxytoluene (E321)	0.402 mg
Benzyl alcohol (E1519)	1 145.700 mg
Diethylene glycol monoethyl ether	

Clear colourless to slightly yellow spot-on solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs weighing 40 to 60 kg

3.2 Indications for use for each target species

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

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

3.3 Contraindications

Do not use on dogs less than 8 weeks old and/or weighing less than 2 kg.
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.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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 veterinary medicinal product efficacy.

The veterinary medicinal 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 veterinary medicinal product will protect against new tick infestations from day 7 to day 28 after application of the veterinary medicinal 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 veterinary medicinal product, even if the veterinary medicinal product is re-applied at the minimum interval of 4 weeks.

3.5 Special precautions for use

Special precautions for safe use in the target species:
For external use only. Do not apply the veterinary medicinal 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 3.9).

It is important to make sure that the veterinary medicinal 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 veterinary medicinal 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.
Do not overdose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Keep the pipettes in original packaging until ready for use and dispose of used pipettes immediately.

People with known hypersensitivity to fipronil or to any of the excipients (see section 2) should avoid contact with the veterinary medicinal product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.
This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact of the veterinary medicinal product with mouth and eyes should be avoided.
After accidental ocular exposure the eye should be rinsed carefully with plain water.
Ingestion of the veterinary medicinal product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the veterinary medicinal 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.

Special precautions for the protection of the environment:
Dogs should not be allowed to swim in watercourses for 2 days after application.
Fipronil may adversely affect aquatic organisms.

Other precautions:
The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings.

3.6 Adverse events

Dogs

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersalivation[1]; Vomiting Application site skin discoloration[2], Application site alopecia[2], Application site pruritus[2], Application site erythema[2] Pruritus, Alopecia Hyperaesthesia[3], Central nervous system depression[3], Neurological signs[3] Respiratory signs

[1] If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.
[2] Transient
[3] Reversible

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder, or its local representative, or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy and lactation

The safety of the veterinary medicinal product has not been established in pregnant or lactating bitches.

Pregnancy and lactation:
Laboratory studies using fipronil have not produced any evidence of teratogenic or fetotoxic effects.
Use only according to the benefit/risk assessment by the responsible veterinarian.
If animals are treated during the lactating period, see section 3.5.

3.8 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.

3.9 Administration routes and dosage

Spot-on use. By topical application to the skin.
Dosage: Make sure you use the correct product, corresponding to the bodyweight of your dog.

- Use 1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight.
  The dosing rate is 6.7 – 10.05 mg fipronil per kg bodyweight.
- Use 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.

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

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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 adverse events may however increase with overdosing. It is therefore recommended to always treat animals with the appropriate pipette size.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AX15

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

After topical application of the veterinary medicinal 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 veterinary medicinal 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. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 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.

5.4 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.

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

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Beaphar B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 41941/4004

8. DATE OF FIRST AUTHORISATION

08 August 2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

February 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 17 March 2026