PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Cardboard box (PP/ALU foil AND Barex® foil and package leaflet included)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 402 mg spot-on

2. STATEMENT OF ACTIVE SUBSTANCES

Fipronil 402.0 mg

3. PACKAGE SIZE

1 x 4.02 ml
2 x 4.02 ml
3 x 4.02 ml
4 x 4.02 ml
6 x 4.02 ml

4. TARGET SPECIES

Dogs weighing 40 to 60 kg.

(40-60 kg)

5. INDICATIONS

The treatment and prevention of flea *(Ctenocephalides felis)* infestations in dogs. The duration of protection against flea infestations is 5 weeks.
The veterinary medicinal product protects against new tick *(Dermacentor reticulatus, Rhipicephalus sanguineus)* infestations in dogs from day 7 to day 28 after application

6. ROUTES OF ADMINISTRATION

Spot-on

Dosage:
1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight.

Use 2 pipettes of 2.68 ml (Fiprotec 268 mg spot-on for large dogs) per dog weighing over 60 kg bodyweight

7. WITHDRAWAL PERIODS

N/A

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use immediately

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
In order to protect from light keep pipette within blister and box until ready for use.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Beaphar B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41941/4004

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Blister (ALU FOIL for PP pipettes)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 402 mg spot-on

(40-60 kg)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 402 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Pipette (PP FOIL and Barex® foil)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 402 mg spot-on

(40-60 kg)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil 402 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fiprotec 402 mg spot-on solution for extra large dogs

2. 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. Target species

Dogs weighing 40 to 60 kg

(40-60 kg)

4. Indications for use

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.

5. Contraindications

Do not use on dogs less than 8 weeks old and/or weighing less than 2 kg.
Do not use on sick animals or animals recovering from illness.
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 allergy to the active substance or to any of the other ingredients.

6. Special warnings

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 before or often after treatment could reduce the effectiveness of the veterinary medicinal product.

The veterinary medicinal product does not prevent ticks from attaching to the animal. In addition, it is not known whether the product will work against existing tick infestations. For this reason, transmission of infectious diseases from the tick to the pet 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 it will work against new tick infestations - beyond 4 weeks following application. Therefore, there may be gaps in protection against ticks after subsequent re-applications of the veterinary medicinal product, even if it is re-applied at the minimum interval of 4 weeks.

Special precautions for safe use in the target species:
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.

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 use

simultaneously with other flea products which are applied directly onto the animal.
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 (allergy) to fipronil or to any of the other ingredients 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.
In case of accidental eye contact, rinse the eye carefully with plain water.
Do not swallow this veterinary medicinal product – it 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:
Fipronil may adversely affect aquatic organisms.
Dogs should not be allowed to swim in watercourses for 2 days after application.

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

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in pregnant or lactating bitches.
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 ‘Special precautions for safe use in the target species.’

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with other flea products which are applied directly onto animal.

Overdose:
Do not overdose.
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.

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

7. Adverse events

Dogs

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Hypersalivation[1] (increased salivation); Vomiting
Application site skin reactions: discoloration[2], alopecia (hair loss)[2], pruritus (itching)[2], erythema (reddening)[2]
Pruritus (itching), Alopecia (hair loss)
Hyperaesthesia (increased sensitivity)[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.

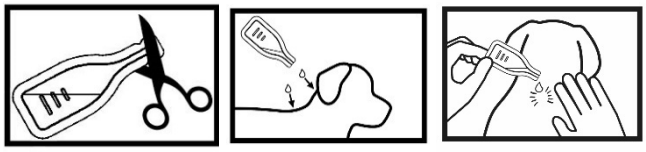
Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder, or its local representative, using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Spot-on use, by topical application to the skin.



Weight your animal carefully before treatment. Make sure you use the correct product, corresponding to the bodyweight of your dog:

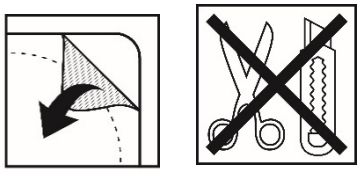
- Use 1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight.
  The dosing rate is 6.7 – 10.05 mg fipronil per kg bodyweight.
- Use 2 pipette of 2.68 ml (Fiprotec 268 mg spot-on for large dogs) per dog weighing over 60 kg
  bodyweight. The dosing rate is up to 8.9 mg fipronil per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

In the absence of safety studies, do not apply more often than every four weeks.

9. Advice on correct administration

Keep the pipettes in the original packaging until required for use.

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.

10. Withdrawal periods

N/A.

11. Special storage precautions

Do not store above 25°C.
Keep pipette within blister and box until ready for use, in order to protect from light. Use immediately after first opening the blister.

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 41941/4004

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Beaphar B.V.
Drostenkamp 3
8101 BX, Raalte
The Netherlands

Manufacturers responsible for batch release:

Beaphar B.V.
Oude Linderteseweg 9
8102 EV Raalte

The Netherlands

Laboratorios Calier, S.A.
Barcelonès, 26 – Pla del Ramassà
08520 Les Franqueses del Vallès
(Barcelona)
Spain

Local representatives and contact details to report suspected adverse events:
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Beaphar UK Ltd.
Rook Tree Farm
Withersfield Road
Great Wratting
Suffolk CB9 7HD
United Kingdom
E: info@uk.beaphar.com
T: +44 (0)1440 715 700

17. Other information

AVM-GSL

Gavin Hall

Approved: 17 March 2026