

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (PP/ALU foil and package leaflet included)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 50 mg spot-on solution for cats
Fipronil

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Fipronil50.0 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 x 0.50 ml
2 x 0.50 ml
3 x 0.50 ml
4 x 0.50 ml
6 x 0.50 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

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

Treatment of tick infestations (*Ixodes ricinus*). Ticks (*Ixodes ricinus*) on the animal at time of treatment will be killed within 48 hours. Treatment does not protect against new tick infestations.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

How to apply Fiprotec:



Route of administration – by topical application to the skin.

Dosage: 1 pipette of 0.5 ml per cat

For external use only. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

n.a.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Use immediately after first opening the blister.

This veterinary medicinal product does not require any special temperature storage conditions.

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

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

The product may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE 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

16. MARKETING AUTHORISATION NUMBER

Vm 41941/4000

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (Barex® foil, no package leaflet included)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 50 mg spot-on solution for cats
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 pipette of 0.5 ml contains:

Active substance:

Fipronil50.0 mg

Excipients:

Butylhydroxyanisole (E-320)0.100 mg

Butylhydroxytoluene (E-321)0.050 mg

Benzyl alcohol (E-1519)142.500 mg

Clear colourless to slightly yellow solution

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 x 0.50 ml

2 x 0.50 ml

3 x 0.50 ml

6 x 0.50 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

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

Treatment of tick infestations (*Ixodes ricinus*). Ticks (*Ixodes ricinus*) on the
animal at time of treatment will be killed within 48 hours. Treatment does not
protect against new tick infestations.

7. METHOD AND ROUTE(S) OF ADMINISTRATION



Route of administration – by topical application to the skin.
Dosage: 1 pipette of 0.5 ml per cat

For external use only.

Keep pipettes in the original packaging until required for use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Before every use, read the information on the inside of the box for full instructions and all warnings, including user warnings.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Use immediately after first opening

This veterinary medicinal product does not require any special temperature storage conditions.

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

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE 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

16. MARKETING AUTHORISATION NUMBER

Vm 41941/4000

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE INSIDE OF THE CARDBOARDBOX

Cardboard box (Barex® foil, no package leaflet included)

1. CONTRAINDICATIONS

In the absence of available data, the product should not be used on kittens less than 8 weeks old and/or weighing less than 1 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 cases of hypersensitivity to the active substance or to any of the excipients.

2. ADVERSE REACTIONS

If licking occurs, a brief period of excessive drooling/salivation 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.

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 inform 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).

3. ADVICE ON CORRECT ADMINISTRATION

Hold 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 until the skin is visible. Place the tip of the pipette on the skin and squeeze gently to empty its contents onto the skin, preferably at two spots, one at the base of the skull and a second 2-3 cm further back.

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 disappear within 24 hours post application.

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

4. SPECIAL WARNING(S), IF NECESSARY

Special warnings for each target species

For optimum control of flea problems in a multi-pet household, 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 infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

Avoid frequent swimming or shampooing of the animal because the maintenance of effectiveness of the product has not been tested in these cases.

Special precautions for use in animals

For external use only. 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.

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.

There may be an attachment of ticks. For this reason transmission of infectious diseases from the tick to the pet cannot be excluded.

Do not apply the product on wounds or damaged skin

Do not use in non-target animals, especially not in rabbits.

The potential toxicity of the product for kittens of less than 8 weeks of age in contact with a treated queen 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 to the animal

User warnings

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

Persons with known hypersensitivity (allergy) to fipronil or any of the other ingredients 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.

In case of accidental eye contact, rinse the eye 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

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

Major incompatibilities

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

Use during pregnancy, lactation or lay

Do not use in pregnant cats or where the cat is providing milk for kittens.

Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effect. The safety of the product has not been established in pregnant and lactating queens. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

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

The risk of experiencing adverse effects may increase with overdosing. Itching may occur following treatment.

Overdose application of the product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

5. DATE ON WHICH THE LABELLING TEXT WAS LAST APPROVED

6. OTHER INFORMATION

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

Not all pack sizes may be marketed.

Manufacturer responsible for batch release:

Laboratorios Calier, S.A.
Barcelonès, 26 – Pla del Ramassà
08520 Les Franqueses del Vallès
(Barcelona)
SPAIN
Telf.: +34 93 849 51 33
Fax.: + 34 93 840 13 98
e-mail: laboratorios@calier.es

Beaphar B.V.
Oude Lindertseweg 9
8102 EV Raalte
Netherlands
Telephone +31 572 348 834
Telefax: +31 572 348 835
E-Mail: hqb@beaphar.com

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister (ALU FOIL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 50 mg spot-on solution for cats
Fipronil



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil50.0 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

- 1 x 0.50 ml
- 2 x 0.50 ml
- 3 x 0.50 ml
- 4 x 0.50 ml
- 6 x 0.50 ml

4. ROUTE(S) OF ADMINISTRATION

Topical application to the skin

5. WITHDRAWAL PERIOD(S)

n.a.

6. BATCH NUMBER

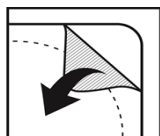
Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.



Extra information:Beaphar B.V.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Pipette (PP foil)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 50 mg fipronil



(optional)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

See alu blister

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

See alu blister

**MINIMUM PARTICULARS TO APPEAR ON PIPETTES AND BLISTERS
(Barex® foil)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPROTEC 50 mg Cats Spot On
Fipronil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Beaphar B.V.

3. EXPIRY DATE

{month/year}

4. BATCH NUMBER

{number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET
(Only included in case of PP/ALU foil)

PACKAGE LEAFLET:
Fiprotec 50 mg spot-on solution for cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release:

Laboratorios Calier, S.A.
Barcelonès, 26 – Pla del Ramassà
08520 Les Franqueses del Vallès
(Barcelona)
SPAIN
Telf.: +34 93 849 51 33
Fax.: + 34 93 840 13 98
e-mail: laboratorios@calier.es

Beaphar B.V.
Oude Lindertseweg 9
8102 EV Raalte
Netherlands
Telephone +31 572 348 834
Telefax: +31 572 348 835
E-Mail: hqb@beaphar.com

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec 50 mg spot-on solution for cats
Fipronil



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

1 pipette of 0.5 ml contains:

Active substance:

Fipronil50.0 mg

Excipients:

Butylhydroxyanisole (E-320)0.100 mg
Butylhydroxytoluene (E-321).....0.050 mg
Benzyl alcohol (E-1519).....142.500 mg

Clear colourless to slightly yellow solution

4. INDICATION(S)

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

Treatment of tick infestations (*Ixodes ricinus*). Ticks (*Ixodes ricinus*) on the animal at time of treatment will be killed within 48 hours. Treatment does not protect against new tick infestations.

5. CONTRAINDICATIONS

In the absence of available data, the product should not be used on kittens less than 8 weeks old and/or weighing less than 1 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 cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

If licking occurs, a brief period of excessive drooling/salivation 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.

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 inform 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).

7. TARGET SPECIES

Cats 

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

How to apply Fiprotec:



Route of administration – by topical application to the skin.

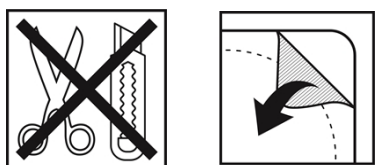
Dosage: 1 pipette of 0.5 ml per cat

For external use only.

Keep pipettes in the original packaging until required for use.

9. ADVICE ON CORRECT 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 until the skin is visible. Place the tip of the pipette on the skin and squeeze gently to empty its contents onto the skin, preferably at two spots, one at the base of the skull and a second 2-3 cm further back.

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 disappear within 24 hours post application.

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

10. WITHDRAWAL PERIOD(S)

n.a.

11. SPECIAL STORAGE PRECAUTIONS

Use immediately after first opening the blister.

This veterinary medicinal product does not require any special temperature storage conditions.

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

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special warnings for each target species:

For optimum control of flea problems 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.

Avoid frequent swimming or shampooing of the animal because the maintenance of effectiveness of the product has not been tested in these cases.

Special precautions for use in animals:

For external use only. 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.

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.

There may be an attachment of ticks. For this reason transmission of infectious diseases from the tick to the pet cannot be excluded.

Do not apply the product on wounds or damaged skin

Do not use in non-target animals, especially not in rabbits.

The potential toxicity of the product for kittens less than 8 weeks of age in contact with a treated queen 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 to the animal

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

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

Persons with known hypersensitivity (allergy) to fipronil or any of the other ingredients 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.

In case of accidental eye contact, rinse the eye 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

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

Major incompatibilities

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

Pregnancy and lactation:

Do not use in pregnant cats or where the cat is providing milk for kittens.

Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effect. The safety of the product has not been established in pregnant and lactating queens. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

Overdose (symptoms, emergency procedures, antidotes):

The risk of experiencing adverse effects may increase with overdosing. Itching may occur following treatment.

Overdose application of the product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

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 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

Not all pack sizes may be marketed.

Approved: 08 August 2019

A handwritten signature in black ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending to the right from the end of the name.