

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box

From 2 days old weighing a minimum of 166 g to a maximum of 10 kg.

The following wording must be prominently displayed on the front of the outer packaging:

Route of administration: spray pump for external use.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Spray 2.5 mg/ml Cutaneous Spray, Solution for Cats and Small Dogs
Fipronil

2. STATEMENT OF ACTIVE SUBSTANCES

What's in this product:

Each ml of FIPROtec® spray contains 2.5 mg of fipronil (active ingredient)

3. PHARMACEUTICAL FORM

Cutaneous Spray, Solution

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cats and Dogs

6. INDICATION(S)

What does this product do?

Fiprotec Spray is for the treatment and prevention of flea (*Ctenocephalices spp.*) and tick (*Ixodes spp, including Ixodes ricinus*) infestations in cats and dogs and the treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*). Killing action against new infestations with adult fleas persists for up to 2 months in cats and up to 3 months in dogs, depending on environmental challenge. The product has a persistent killing action for up to one month against ticks, depending on the level of environmental challenge.

Optional (to print on front side of the box):

- Kills fleas, ticks and biting lice

7. METHOD AND ROUTE(S) OF ADMINISTRATION

How do I use this product?

Read the package leaflet before use.

It is essential that the weight of the animal(s) to be treated is accurately determined before use of the product.

It is important to dampen the coat down to the skin. Depending on the length of hair, apply 3 to 6 ml per kg bodyweight, (7.5 to 15mg of active ingredient per kg bodyweight) i.e. 6 to 12 pump applications per kg bodyweight of the 100ml presentation.

Cats/dogs weighing	Short hair	Long hair
166 g	1 pump	2 pumps
333 g	2 pumps	4 pumps
500 g	3 pumps	6 pumps
666 g	4 pumps	8 pumps
832 g	5 pumps	10 pumps
1.0 kg	6 pumps	12 pumps
1.5 kg	9 pumps	18 pumps
2.0 kg	12 pumps	24 pumps
2.5 kg	15 pumps	30 pumps
3.0 kg	18 pumps	36 pumps
3.5 kg	21 pumps	42 pumps
4.0 kg	24 pumps	48 pumps
5.0 kg	30 pumps	60 pumps
6.0 kg	36 pumps	72 pumps
7.0 kg	42 pumps	84 pumps
8.0 kg	48 pumps	96 pumps
9.0 kg	54 pumps	108 pumps
10.0 kg	60 pumps	120 pumps

Do not exceed the recommended dosage.

The 100ml bottle contains 200 pumps.

Spray the entire body of the animal, and apply from a distance of approximately 10-20 cm.

Apply against the lay of the hair and make sure that the entire coat of the animal is dampened. Ruffle the coat, especially in long haired animals, so that the product penetrates down to the skin.

For treatment of the head region, and when treating young or nervous pets, application may be carried out by spraying onto a gloved hand and rubbing the product into the coat. This is because it is important to avoid the product coming into contact with the eyes and mouth. Allow to dry naturally. Do not towel dry.

The minimum dose for the product is one pump. Therefore, this product is only suitable for puppies and kittens from 2 days old that weigh more than 166 g. Very young puppies and kittens are unable to regulate their body temperature and use of the product will have a cooling effect. For this reason, care must be taken to keep these individuals warm after treatment whilst remembering to keep treated animals away from fires or other sources of heat as the product is highly flammable.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use for full instructions and all warnings.

Special warnings for each target species:

Avoid contact with the animal's eyes.

Do not spray directly onto areas of broken skin.

Allow treated animals to dry in a well ventilated room.

Do not confine animals in an enclosed space or pet carrier until the coat is totally dry.

In the absence of specific tolerance and efficacy data, the product is not recommended for the treatment of species other than cats and dogs.

Do not use for direct treatment of the household environment or animal bedding.

Given the volume delivered by the spray pump (0.5ml/pump) the product is suitable for use in cats and dogs up to 5-10kg bodyweight, depending on the length of hair but not adequate for medium and large dogs.

Special precautions for use in animals:

It is important to make sure that animals do not lick each other following treatment.

There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

User Safety

People with asthma or a known hypersensitivity to insecticides or alcohol should avoid contact with the veterinary medicinal product. This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided.

Avoid contents coming into contact with the fingers. **Wear disposable PVC or nitrile gloves during treatment of animals. It is also recommended to wear a waterproof apron for the protection of clothing.**

Dispose of gloves after use and then wash hands with soap and water.

If clothing or the animal's bedding becomes heavily wetted with the product, it should be removed and washed before re-use.

If skin contact occurs, wash immediately with soap and water. If irritation occurs, seek medical advice.

After accidental eye exposure, the eye should be rinsed carefully with clean water.

Treated animals should not be handled until the fur is dry, and children should not be allowed to play with treated animals until the fur 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 are not allowed to sleep with owners, especially children.

Spray animals in the open air or in a well-ventilated room.
Do not breathe spray. Do not smoke, drink or eat during application.

Treatment of multiple animals: Good ventilation is particularly important where several animals are to be treated. Treat multiple animals outside, or reduce the build-up of vapour by removing the animals from the treatment room while the alcohol is evaporating and ensure that the treatment room is well ventilated between individual treatments. In addition, ensure that the drying room is well ventilated and avoid housing several recently treated animals within the same air space.

Environmental Safety

Fipronil may adversely affect aquatic organisms.
Dogs should not be allowed to swim in watercourses for 2 days after application.

Read the package leaflet before use.

Is this product suitable for my pet?

Given the volume delivered by the spray pump (0.5ml/pump), the product is suitable for use in cats and dogs up to 5-10 kg bodyweight (depending on the length of hair) but not appropriate for medium and large dogs. It is important to dampen the coat down to the skin. The spray is safe to use on lactating dogs. Do not use on pregnant cats and dogs or on nursing cats. Do not use simultaneously with other flea products which are applied directly onto the animal. In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other medicinal products.

Contraindications

Do not use on sick or recovering animals. **Do not use on rabbits as adverse reactions and even death could occur.** Do not use in cases of hypersensitivity (allergy) to the active substance or to any of the other ingredients.

Image of rabbit with 'no symbol' to appear on front of packaging:



10. EXPIRY DATE

EXP {DD/MM/YY}

Once opened use within 1 year.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle.

11. SPECIAL STORAGE CONDITIONS

Highly flammable.
Do not store above 25 °C.

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

Read the package leaflet for disposal information.

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41941/5002

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE Bottle (100ml)

For dogs and cats from 2 days old weighing a minimum of 166 g to a maximum of 10 kg.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Spray 2.5 mg/ml Cutaneous Spray, Solution for Cats and Small Dogs
Fipronil

2. STATEMENT OF ACTIVE SUBSTANCES

Fipronil 2.5 mg/ml

3. PHARMACEUTICAL FORM

Cutaneous Spray, Solution

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cats and Dogs

6. INDICATION(S)

Treatment and prevention of flea (*Ctenocephalides* spp.) and tick (*Ixodes* spp., including *Ixodes ricinus*) infestations in cats and dogs.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

Killing action against new infestations with adult fleas persists for up to 2 months in cats and up to 3 months in dogs, depending on environmental challenge.

The product has a persistent killing action for up to one month against ticks, depending on the level of environmental challenge.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Apply 3 to 6 ml per kg bodyweight. The 100ml bottle contains:

- Approximately 3 to 6 treatments for a dog weighing 5 kg, depending on hair length;
- Approximately 8 treatments for a short haired cat weighing 4 kg;
- Approximately 2 treatments for a long haired dog weighing 8 kg.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {DD/MM/YY}

Once opened use within 1 year by ____/____

11. SPECIAL STORAGE CONDITIONS

Highly flammable.

Do not store above 25 °C.

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

Disposal: read package leaflet.

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41941/5002

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Fiprotec Spray 2.5 mg/ml Cutaneous Spray, Solution for Cats and Small Dogs

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
Tel: +31 (0) 572 348 834

Manufacturer responsible for batch release:

Beaphar B.V.
Oude Linderteseweg 9
8102 EV Raalte
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Spray 2.5 mg/ml Cutaneous Spray, Solution for Cats and Small Dogs
Fipronil

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

Each ml of solution contains:

Active substance:

Fipronil 2.5 mg

4. INDICATION(S)

Treatment and prevention of flea (*Ctenocephalides* spp.) and tick (*Ixodes* spp., including *Ixodes ricinus*) infestations in cats and dogs.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

Killing action against new infestations with adult fleas persists for up to 2 months in cats and up to 3 months in dogs, depending on environmental challenge.

The product has a persistent killing action for up to one month against ticks, depending on the level of environmental challenge.

5. CONTRAINDICATIONS

Do not use on sick or recovering animals

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 salivation may be observed due mainly to the nature of the carrier.

Among the extremely rare suspected adverse reactions, temporary skin reactions such as reddening, itching or hair loss have been reported after use. Exceptionally, excessive salivation, reversible neurological signs (excessive sensitivity, depression, nervous signs), vomiting or respiratory signs have been observed 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.

7. TARGET SPECIES

Cats and dogs

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

Route of administration: spray pump for external use.

Dosage: It is important to dampen the coat down to the skin. Depending on the length of hair, apply 3 to 6 ml per kg bodyweight, (7.5 to 15mg of active ingredient per kg bodyweight) i.e. 6 to 12 pump applications per kg bodyweight of the 100ml presentation.

It is essential that the weight of the animal(s) to be treated is accurately determined before use of the product.

Cats/dogs weighing	Short hair	Long hair
166 g	1 pump	2 pumps
333 g	2 pumps	4 pumps
500 g	3 pumps	6 pumps
666 g	4 pumps	8 pumps
832 g	5 pumps	10 pumps
1.0 kg	6 pumps	12 pumps
1.5 kg	9 pumps	18 pumps
2.0 kg	12 pumps	24 pumps
2.5 kg	15 pumps	30 pumps
3.0 kg	18 pumps	36 pumps
3.5 kg	21 pumps	42 pumps
4.0 kg	24 pumps	48 pumps
5.0 kg	30 pumps	60 pumps
6.0 kg	36 pumps	72 pumps
7.0 kg	42 pumps	84 pumps
8.0 kg	48 pumps	96 pumps
9.0 kg	54 pumps	108 pumps
10.0 kg	60 pumps	120 pumps

The 100ml bottle contains:

- Approximately 3 to 6 treatments for a dog weighing 5 kg, depending on hair length;
- Approximately 8 treatments for a short haired cat weighing 4 kg;
- Approximately 2 treatments for a long haired dog weighing 8 kg.

Properties: The formulation contains a coating agent. Therefore, spraying builds up a film.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

9. ADVICE ON CORRECT ADMINISTRATION

Method of administration:

Spray the entire body of the animal, and apply from a distance of approximately 10-20cm.

Apply against the lay of the hair and make sure that the entire coat of the animal is dampened. Ruffle the coat, especially in long haired animals, so that the product penetrates down to the skin.

For treatment of the head region, and when treating young or nervous pets, application may be carried out by spraying onto a gloved hand and rubbing the product into the coat. Allow to dry naturally. Do not towel dry.

The minimum dose for the product is one pump. Therefore, this product is only suitable for puppies and kittens from 2 days old that weigh more than 166 g. Very young puppies and kittens are unable to regulate their body temperature and use of the product will have a cooling effect. For this reason, care must be taken to keep these individuals warm after treatment whilst remembering to keep treated animals away from fires or other sources of heat as the product is highly flammable.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Highly flammable.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle.

Shelf life after first opening the container: 1 year.

The discard date (1 year after opening) should be recorded in the space available on the label. Any product remaining after this date, should be discarded.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Do not exceed the recommended dosage.

Avoid contact with the animal's eyes.

Do not spray directly onto areas of broken skin.

Allow treated animals to dry in a well ventilated room.

Do not confine animals in an enclosed space or pet carrier until the coat is totally dry.

In the absence of specific tolerance and efficacy data, the product is not recommended for the treatment of species other than cats and dogs.

For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the product. Bathing or shampooing up to four times in two months has been shown not to significantly reduce the remaining effect of the product. Monthly treatment is recommended when more frequent shampooing is carried out.

For optimal control of flea infestations in multi-pet households, all dogs and cats in the household should be treated at the same time.

Fleas from pets often infest the animal's basket, bedding and regular resting areas, such as carpets and soft furnishings. In cases of massive infestation and when initiating control measures these areas should also be treated with a suitable insecticide, and vacuumed regularly.

The product is not suitable for direct treatment of the environment.

Given the volume delivered by the spray pump (0.5ml/pump) the product is very suitable for use in cats and dogs up to 5-10kg bodyweight, depending on the length of hair (see also section 8) but not adequate for medium and large dogs."

Special precautions for use in animals:

It is important to make sure that animals do not lick each other following treatment.

There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

The product is highly flammable, it is important to keep treated animals away from fires or other sources of heat, and surfaces likely to be affected by the alcohol spray, for at least 30 minutes following spraying and until the fur is totally dry. Do not spray on a naked flame or any incandescent material.

For external use only.

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

People with asthma or a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with the veterinary medicinal product.

This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided.

Avoid contents coming into contact with the fingers. **Wear disposable PVC or nitrile gloves during treatment of animals. It is also recommended to wear a waterproof apron for the protection of clothing.**

Dispose of gloves after use and then wash hands with soap and water.

If clothing or the animal's bedding becomes wetted with the product, it should be removed and washed before re-use.

If skin contact occurs, wash immediately with soap and water. If irritation occurs, seek medical advice.

After accidental eye contact, the eye should be rinsed with clean water.

Treated animals should not be handled until the fur is dry, and children should not be allowed to play with treated animals until the fur 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 are not allowed to sleep with owners, especially children.

Spray animals in the open air or a well ventilated room.

Do not breathe spray. Do not smoke, drink or eat during application.

Treatment of more than one animal: Good ventilation is particularly important where several animals are to be treated. Treat the animals outside, or reduce the build-up of vapour by removing the animals from the treatment room while the alcohol is evaporating and ensure that the treatment room is well ventilated between individual treatments. In addition, ensure that the drying room is well ventilated and avoid housing several recently treated animals within the same air space.

Other precautions:

Environmental precautions: Fipronil may adversely affect aquatic organisms.

Dogs should not be allowed to swim in watercourses for 2 days after application.

Pregnancy, Lactation and Lay:

The spray is safe to use on lactating dogs.

Do not use on pregnant cats and dogs or on nursing cats.

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.

Overdose (symptoms, emergency procedures, antidotes):

The risk of experiencing adverse effects may increase when overdosing, so animals should always be treated with the correct dose according to bodyweight.

In case of overdosing, appropriate symptomatic treatment should be started by a veterinarian.

Incompatibilities:

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

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.

Fipronil 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

July 2021

15. OTHER INFORMATION

100ml bottle

Approved 29 July 2021

A handwritten signature in black ink, appearing to read "Hunter.", is written below the approval date.