

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box containing 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fipronil spot-on solution by Virbac 50 mg

**2. STATEMENT OF ACTIVE SUBSTANCES**

One 0.5 ml pipette contains:  
Fipronil 50 mg

**3. PACKAGE SIZE**

1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes



**4. TARGET SPECIES**

Cats.

**5. INDICATIONS**

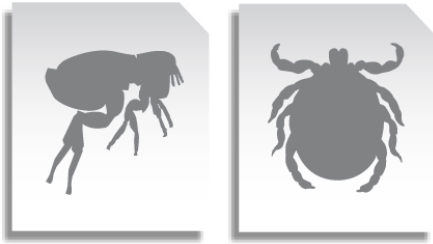
**For products not subject to veterinary prescription:**

Treatment of flea (*Ctenocephalides* spp.) and tick (*Dermacentor reticulatus*) infestations.

The veterinary medicinal product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides felis*).

The veterinary medicinal product has a persistent acaricidal efficacy for up to 2 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus*, *Dermacentor reticulatus*). If ticks of some species (*Rhipicephalus sanguineus* and *Ixodes ricinus*) are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.



Fleas & Ticks

**6. ROUTES OF ADMINISTRATION**

External use only.



**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp.{mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

Store below 30°C.  
Store in a dry place.  
Store in the original package.

**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**

VIRBAC

**14. MARKETING AUTHORISATION NUMBERS**

Vm 05653/3018

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**1 blister**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fipronil by Virbac



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

50 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

1 pipette

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fipronil by Virbac



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

50 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

## **B. PACKAGE LEAFLET**



## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Fipronil spot-on solution by Virbac 50 mg for cats

### 2. Composition

One 0.5 ml pipette contains:

#### Active substance:

Fipronil 50 mg

#### Excipients:

Butylhydroxyanisole (E320) 0.1 mg  
Butylhydroxytoluene (E321) 0.05 mg

Clear, colourless to yellow spot-on solution.

### 3. Target species

Cats.

### 4. Indications for use

Treatment of flea (*Ctenocephalides* spp.) and tick (*Dermacentor reticulatus*) infestations.

The veterinary medicinal product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides felis*).

The veterinary medicinal product has a persistent acaricidal efficacy for up to 2 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus*, *Dermacentor reticulatus*). If ticks of some species (*Rhipicephalus sanguineus* and *Ixodes ricinus*) are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.

## **5. Contraindications**

In the absence of available data, the veterinary medicinal product should not be used on kittens less than 2 months old and/or weighing less than 1 kg.

Do not use on sick (systemic diseases, fever...) or convalescent animals.

Do not use in rabbits, as adverse drug reactions and even death could occur.

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

## **6. Special warnings**

### Special warnings:

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.

The veterinary medicinal product does not prevent ticks from attaching to the animals. If the animal has been treated prior to exposure to the ticks, the ticks will be killed in the first 24-48 hours after attachment. This will usually be prior to engorgement, minimising but not excluding the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may be removed with a gentle pull.

It is advisable to avoid frequent bathing or shampooing because the maintenance of effectiveness of the veterinary medicinal product in these cases has not been tested.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other cats in the household are recommended.

For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

### Special precautions for safe use in the target species:

Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

Do not apply the product on wounds or damaged skin.

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

This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided.

In the case of accidental eye contact, immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

Wash hands after use.

Do not smoke, drink or eat during application.

People with known hypersensitivity to fipronil or excipients should avoid contact with the veterinary medicinal product.

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.

Other precautions:

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

Pregnancy and lactation:

Laboratory studies in cats have not produced any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this product in pregnant and lactating queens. Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose:

No adverse effects were observed in target animal safety studies in cats and kittens aged 2 months and older and weighing about 1 kg treated at five times the recommended dose (daily therapeutic dose applied on five consecutive days) for three consecutive months except for itching and vomiting that occurred once. The risk of adverse effects may increase in cases of over-dose.

## 7. Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Application site reaction<sup>1</sup> (skin squamosis (scaly skin), alopecia (hair loss), pruritus (itching), erythema (reddening))  
Generalised itching, Alopecia general  
Hypersalivation<sup>2</sup> (increased salivation)  
Neurological disorders<sup>3</sup> (e.g. Hyperaesthesia (increased sensitivity to stimuli), central nervous system depression and neurological symptoms)  
Vomiting

<sup>1</sup>Transient cutaneous reactions at the application site.

<sup>2</sup> If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

<sup>3</sup>Reversible symptoms.

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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

Route of administration and dosage:

External use only.

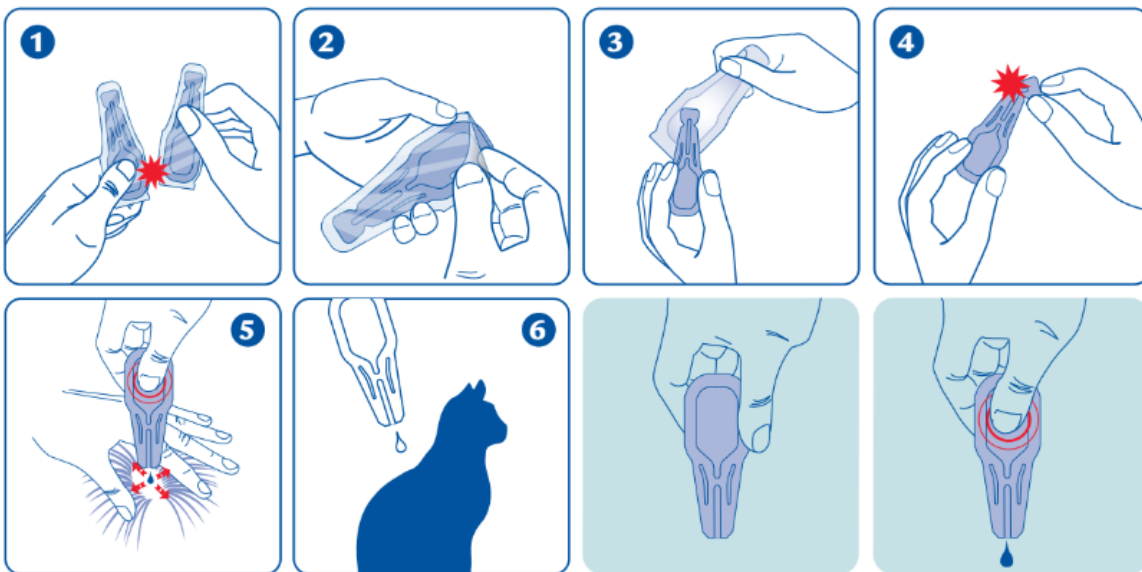
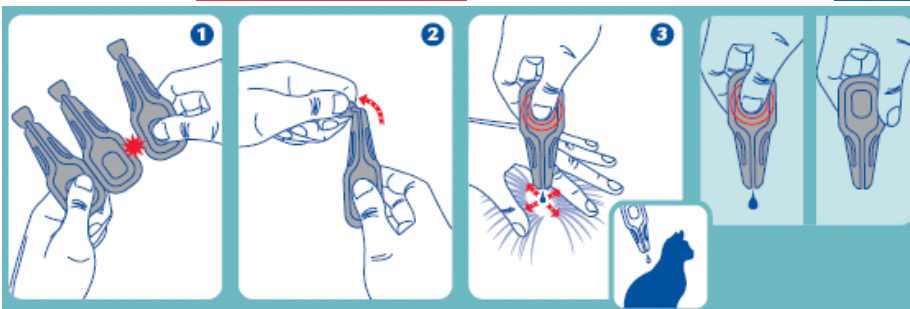
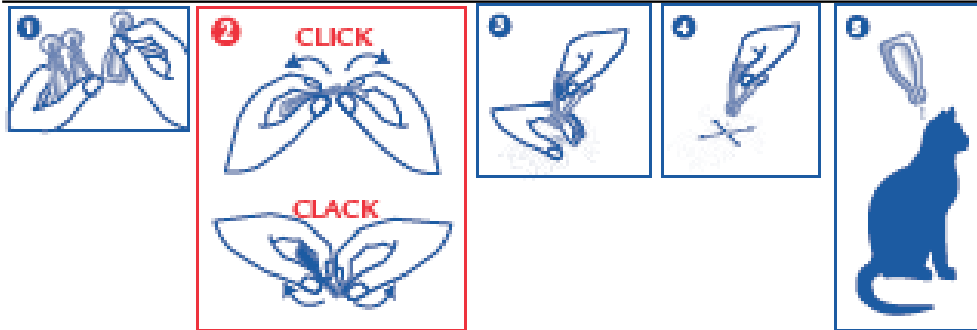
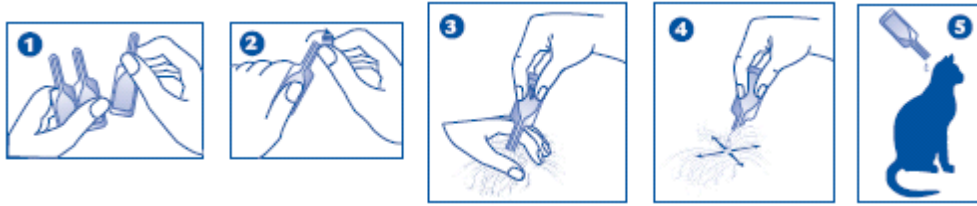
Administer by topical application to the skin 1 pipette of 0.5 ml per animal.

Method of administration:

*Thermoformed pipettes:*

Hold the pipette upright. Tap the narrow part of the pipette to ensure that the contents are within the main body of the pipette. Break the snap-off top of the spot-on pipette along the scored line.

Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents Repeat this procedure at one or two different points along the cat's back, preferably at the base of the head and between the shoulders.



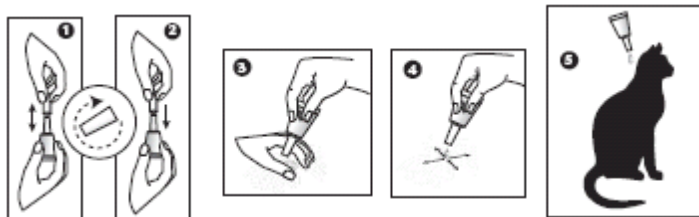
(Note : the shape of the marketed pipettes can be different as well as the pictures on the marketed boxes/package leaflets.)

***Polypropylene pipettes:***

Remove the pipette from the blister packaging. Hold the pipette in an upright position, twist and pull the cap off. Turn the cap around and place the other end of the cap back on the pipette. Twist the cap to break the seal, then remove the cap from the pipette.

Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents. Repeat this

procedure at one or two points along the cat's back, preferably at the base of the head and between the shoulders.



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.

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.

White deposits may also be seen at the site for up to 48 hours after application.

(Note : There will be 2 insert leaflets, one for each type of pipette. However, for practical reasons both are stated on 1 insert leaflet.)

## 9. Advice on correct administration

### Treatment schedule:

For optimal control of flea and/or tick infestation the treatment schedule can be based on the local epidemiological situation.

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

## 10. Withdrawal periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach of children.

Store below 30°C.

Store in a dry place.

Store in the original package.

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

Do not remove from blister until required for use.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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.

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

Do not contaminate ponds, waterways or ditches with the product or empty container.

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

### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription. *[Applicable to BE BG CY EL HU IE SE (8, 12, 24, 30, 60, 90 or 150 pipettes) SI UK (NI)]*

Veterinary medicinal product not subject to prescription. *[Applicable to AT CZ DE DK EE ES FI FR IT LT LU LV NL PL PT RO SE (1, 2, 3, 4 or 6 pipettes) SK]*

### **14. Marketing authorisation numbers and pack sizes**

Vm 05653/3018

Thermoformed pipettes boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

Polypropylene pipettes: blister cards or boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

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](http://www.gov.uk).

### **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Virbac  
1ère avenue - 2065m - LID  
06516 Carros Cedex  
France

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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*Gavin Hall*

Approved: 28 June 2024