

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 268 mg

2. STATEMENT OF ACTIVE SUBSTANCES

One 2.68 ml pipette contains:
Fipronil 268 mg

3. PACKAGE SIZE

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



4. TARGET SPECIES

Large dogs > 20-40 kg

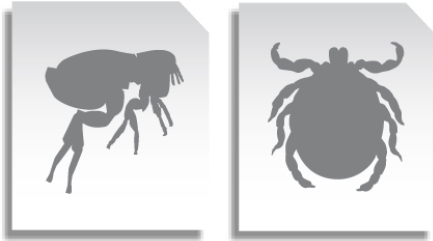
5. INDICATIONS

For products not subject to veterinary prescription.

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

Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. The veterinary medicinal product has a persistent acaricidal efficacy for up to 4 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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

Vm 05653/3021

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1 blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipronil by Virbac



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

268 mg
> 20-40 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON PIPETTES

1 pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipronil by Virbac



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

268 mg
> 20-40 kg

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 100 mg/ml for small, medium, large and very large dogs

2. Composition

Active substance:

Each ml contains 100 mg fipronil.

Each pipette delivers the following amount:

	Unit dose	Fipronil
for small dogs	0.67 ml	67 mg
for medium dogs	1.34 ml	134 mg
for large dogs	2.68 ml	268 mg
for very large dogs	4.02 ml	402 mg

Excipients:

	Butylhydroxyanisole E320	Butylhydroxytoluene E321
for small dogs	0.134 mg/pipette	0.067 mg/pipette
for medium dogs	0.268 mg/pipette	0.134 mg/pipette
for large dogs	0.536 mg/pipette	0.268 mg/pipette
for very large dogs	0.804 mg/pipette	0.402 mg/pipette

Clear, colourless to yellow solution.

3. Target species

Dogs.

4. Indications for use

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

Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. The veterinary medicinal product has a persistent acaricidal efficacy for up to 4 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

Do not use on puppies less than 2 months old and /or weighing less than 2kg in the absence of available data.

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

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

This veterinary medicinal product is specifically developed for dogs. 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 excipients.

6. Special warnings

Special warnings:

Shampooing an hour prior to treatment does not affect the efficacy of the veterinary medicinal product against fleas.

Bathing/immersion in water within two days after application of the veterinary medicinal product should be avoided. Weekly immersion in water for one minute reduces the period of persistent insecticidal efficacy against fleas by one week and therefore it is advisable to avoid frequent swimming and shampooing.

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.

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.

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

For optimal control of flea infestation in 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:

Animals should be weighed accurately prior to treatment.

Avoid contact with the animal's eyes. In the 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.

Do not apply the veterinary medicinal 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.

Do not smoke, drink or eat during application.

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

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.

Special precautions for the protection of the environment:

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses 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:

Laboratory studies in dogs have not produced any evidence of teratogenic or embryotoxic effects.

Studies have not been carried out with this veterinary medicinal 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 2 month-old puppies, growing dogs and dogs weighing about 2 kg treated with the therapeutic dose on five consecutive days. The risk of adverse effects (see section 3.6) may increase in cases of overdose.

7. Adverse events

Dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reaction ¹ (e.g. skin hair coat, discolouration, alopecia, pruritus (itching), erythema (reddening))
Generalised itching, Alopecia (hair loss) general
Hypersalivation (increased salivation) ²
Neurological disorder ³ (e.g. Hyperesthesia (increased sensitivity to stimuli), central nervous system depression and neurological symptoms)
Vomiting
Respiratory tract disorders

¹Transient cutaneous reactions on the application site.

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

³Reversible symptoms.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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:

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

Route of administration and dosage:

External use only.

Administer by topical application to the skin according to the bodyweight as follows,

* 1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight

* 1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight

* 1 pipette of 2.68 ml per dog weighing over 20 kg and up to 40 kg bodyweight

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

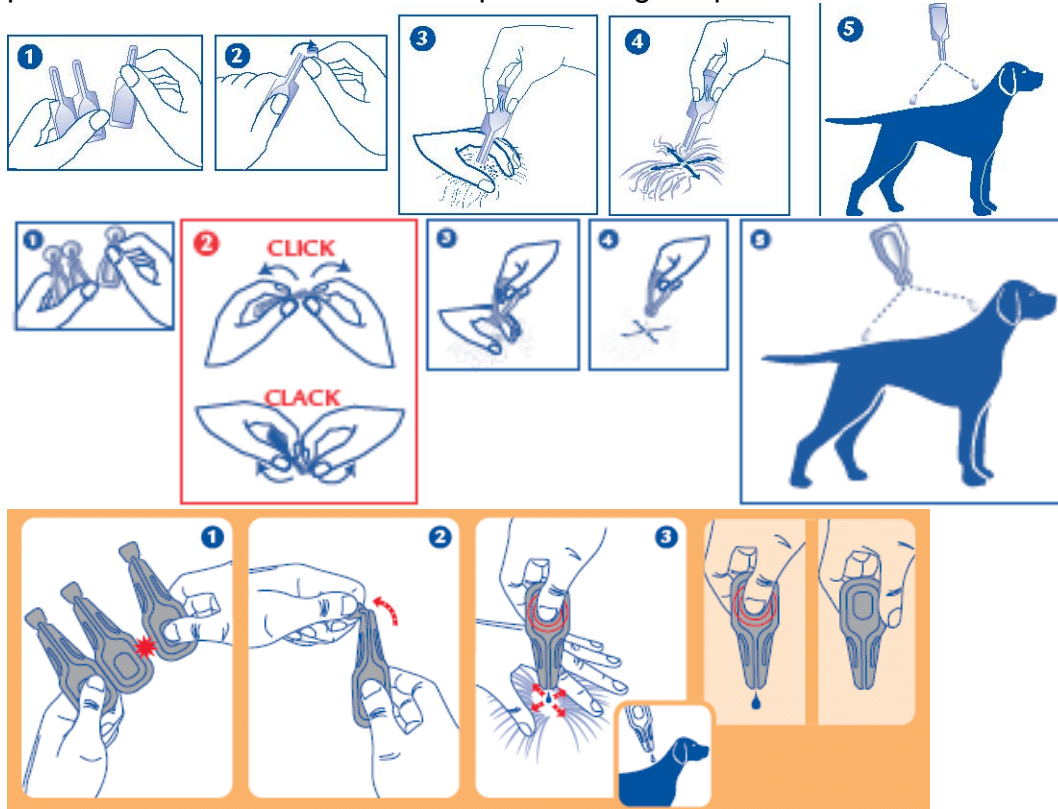
For dogs over 60 kg use two pipettes of 2.68 ml.

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 pet's back.

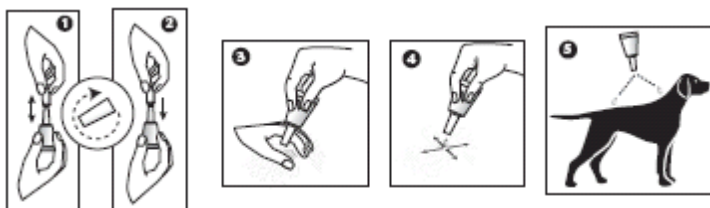


(Note : the shape of the marketed pipettes can be different as well as the pictures on the marketed boxes/package leaflets.)

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 pet's back.



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.

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 disappear within 24 hours post 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 reach and sight 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 carton and pipette after "Exp".

Do not remove from blister until required for use.

The expiry date refers to the last day of that month

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 or other aquatic organisms.

Do not contaminate ponds, waterways or ditches with the veterinary medicinal 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 05653/3021

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.

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.

Gavin Hall

Approved: 28 June 2024