

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 1 individual pipette placed in overblister
Box containing 4 individual pipettes placed in 2 overblisters
Box containing 24 individual pipettes placed in 12 overblisters
Box containing 60 individual pipettes placed in 30 overblisters



Fleas, Ticks, Flea eggs



1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPRONIL PYRIPROXYFEN VIRBAC 50 mg/60 mg spot-on solution


2. STATEMENT OF ACTIVE SUBSTANCES

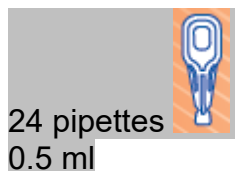
Each 0.5 ml pipette contains:

Fipronil	50 mg
Pyriproxyfen	60 mg

3. PACKAGE SIZE

1 pipette 
0.5 ml

4 pipettes 
0.5 ml



4. TARGET SPECIES

Cats

5. INDICATIONS

For products not subject to veterinary prescription.

To be used against infestations with fleas alone or in association with ticks.

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

Store in a dry place.

Keep the blister pack in the outer carton in order to protect from light.



30°C

[optional]

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.



[optional]

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

Vm 05653/3005

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Dispensing envelope with a capacity of either one or two 2-pipette blister(s) (to be included in large boxes only)



Fleas, Ticks, Flea eggs



This intermediate package is intended to contain at least one 2-pipette blister (and up to two 2-pipette blisters).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPRONIL PYRIPROXYFEN VIRBAC spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.5 ml pipette contains:

Fipronil	50 mg
Pyriproxyfen	60 mg

Each 1 ml pipette contains:

Fipronil	100 mg
Pyriproxyfen	120 mg

3. PACKAGE SIZE

This intermediate package is intended to contain at least one 2-pipette blister (and up to two 2-pipette blisters).

4. TARGET SPECIES

Cats

5. INDICATIONS

For products not subject to veterinary prescription.

To be used against infestations with fleas alone or in association with ticks.

6. ROUTES OF ADMINISTRATION

Spot-on use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

For lot number and expiry date, please refer to the overblister or pipette.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

Store in a dry place.

Keep the blister pack in the envelope in order to protect from light.



30°C

[optional]

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.



[optional]

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

Vm 05653/3005

15. BATCH NUMBER

For lot number and expiry date, please refer to the overblister or pipette.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Overblister packed in 1-pipette blister or 2-pipette blisters divisible per pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPRONIL PYRIPROXYFEN VIRBAC



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50 mg/60 mg
1-6 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Individual Pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPRONIL PYRIPROXYFEN VIRBAC



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50 mg/60 mg
1-6 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 Pyriproxyfen Virbac 50 mg/60 mg spot-on solution for cats
Fipronil Pyriproxyfen Virbac 100 mg/120 mg spot-on solution for very large cats

2. Composition

Each pipette contains:	Active substances		Excipients	
Pipette volume (single dose unit)	Fipronil	Pyriproxyfen	BHA*	BHT**
0.5 ml	50 mg	60 mg	0.1 mg	0.05 mg
1 ml	100 mg	120 mg	0.2 mg	0.10 mg

*: Butylhydroxyanisole E320, **: Butylhydroxytoluene E321

Clear, colourless to yellowish solution.

3. Target species

Cats

4. Indications for use

In cats, to be used against infestations with fleas alone or in association with ticks.

Against fleas:

Treatment and prevention of infestations by fleas (*Ctenocephalides felis*). One treatment prevents further infestations for 5 weeks.

Prevention of the multiplication of fleas by preventing flea eggs developing into adult fleas for 12 weeks after application.

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.

Against ticks:

Treatment of infestations by ticks (*Ixodes ricinus* and *Rhipicephalus turanicus*). One treatment provides persistent acaricidal efficacy for one week.

If ticks are present at the time of application, not all ticks may be killed within 48 hours.

5. Contraindications

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

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

6. Special warnings

Special warnings:

Wetting of the haircoat with water 2 hours before veterinary medicinal product application and twice during the claimed period of efficacy against fleas (at two week intervals against adult fleas or four week intervals against developing flea stages) was investigated during two laboratory studies. Wetting of the haircoat with water as described did not adversely affect veterinary medicinal product effectiveness.

The impact of shampooing on veterinary medicinal product effectiveness has not been investigated. If a cat requires shampooing it is recommended that this is done before applying the veterinary medicinal product.

At the beginning of the control measures, in the case of an infestation, the animal's basket, bedding and regular resting areas such as carpets and soft furnishings should be treated, with a suitable insecticide and vacuumed regularly.

To reduce environmental flea challenge, all animals living in the same household should also be treated with a suitable flea control veterinary medicinal product.

The veterinary medicinal product does not prevent ticks from attaching to animals. If the animal has been treated prior to exposure to the ticks, the ticks will be killed within 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. Any remaining ticks should be carefully removed, ensuring that their mouth parts are not left within the skin.

Special precautions for safe use in the target species:

For external use only.

Do not administer orally.

Animals should be weighed accurately prior to treatment.

The safety of the veterinary medicinal product has not been established in cats younger than 10 weeks of age or in cats weighing less than 1.0 kg.

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

Care should be taken to apply the veterinary medicinal product correctly as described under section "Dosage for each species, routes and method of administration". Do not apply the veterinary medicinal product on wounds or damaged skin. It is important to make sure that the veterinary medicinal product is applied directly onto an area of dry skin where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

The use of the veterinary medicinal product has not been studied in sick or debilitated cats. Use in sick or debilitated animals only according to the benefit-risk assessment by the responsible veterinarian.

In the absence of additional safety studies, do not repeat the treatment at intervals of less than 4 weeks.

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

The veterinary medicinal product may cause neurotoxicity. The veterinary medicinal product may be harmful if swallowed.

Avoid ingestion including hand to mouth contact.

Do not smoke, drink or eat during application.

In the event of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

This veterinary medicinal product can cause eye and mucous membrane irritation.

Avoid contact with skin, eye and mouth, including hand to eye contact.

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

Wash hands after use.

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.

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

For animal treatment only.

Other precautions:

The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

Laboratory studies using fipronil and pyriproxyfen have not produced any evidence of teratogenic or embryotoxic effects.

The safety of the veterinary medicinal product has not been established in pregnant and lactating queens.

Use in pregnant and lactating animals only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

No serious adverse effects were observed in a target animal safety study in 10-week old kittens treated with up to 5 times the maximum recommended dose 3 times at intervals of 4 weeks and with the maximum recommended dose 6 times at intervals of 4 weeks.

The risk of experiencing adverse events (see adverse events section) may however increase with overdosing, so animals should always be treated with correct pipette size according to bodyweight.

7. Adverse events

Cats

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reaction ¹ (e.g., Application site skin squamosis, Application site alopecia, Application site pruritus (itching), Application site erythema (redness), Application site skin discolouration)
Generalised itching, Alopecia (hair loss)
Hypersalivation, Vomiting
Neurological disorder ² (e.g. Hyperaesthesia (increased sensitivity to stimuli), Central nervous system depression, Neurological symptoms)
Respiratory signs
Undetermined frequency (Cannot be estimated from the available data)
Application site greasy fur ^{1,3} , Application site skin scaling ^{1,3,4}

¹Transient

²Reversible

³Cosmetic effect

⁴Slight

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: {national system details}

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

Spot-on use.

Dosage:

The minimum recommended dose is 8.3 mg fipronil/kg b.w. and 10 mg pyriproxyfen/kg b.w..

For a cat weighing at least 1 kg and up to 6 kg apply one pipette of 0.5 ml per cat.

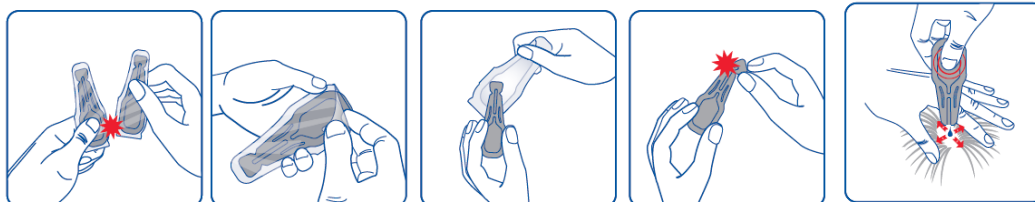
For a cat weighing over 6 kg a recommended dose of 1 ml should be applied, which can be achieved by applying one pipette of 1 ml (or alternatively two pipettes of 0.5 ml).

Cat weight	Pipette volume		Fipronil (mg)	Pyriproxyfen (mg)
1-6 kg	0.5 ml		50	60
>6-12 kg	1 ml		100	120

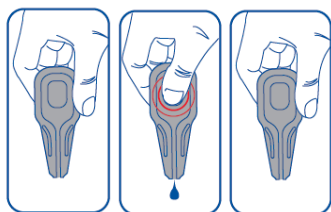
Method of administration:

Remove the pipette from the overblister. 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 coat on the back of neck area until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents evenly at one or two spots. Ensure the solution is applied to healthy skin only and avoid superficial application to the cat's hair or run off, especially in large cats (over 6 kg).



Drop stop system (the veterinary medicinal product is released only by pressing the body of the pipette).



9. Advice on correct administration

For optimal control of flea and tick infestations and flea multiplication, the treatment schedule can be based on the local epidemiological situation. However, in the absence of additional safety studies, do not repeat the treatment at intervals of less than 4 weeks (see subsection Overdose in section Special warnings).

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30°C.

Store in a dry place.

Keep the blister pack in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label 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 or household waste.

The 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

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 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 subject to prescription (24 or 60 pipettes).

14. Marketing authorisation numbers and pack sizes

Vm 05653/3005

Vm 05653/3006

Boxes of 1, 4, 24 and 60 pipettes (large boxes including envelopes intended for dispensing a reduced number of pipettes). [this sentence will be deleted in case the dispensing envelope cannot be accepted].

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
1^{ère} avenue 2065m LID
06516 Carros
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.

17. Other information

Pyriproxyfen is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues. It prevents, by contact, the emergence of adult insects by blocking the development of eggs (ovicidal effect), larvae and pupae (larvicidal effect), which are subsequently eliminated.

Combination of fipronil and pyriproxyfen provides an insecticidal and acaricidal activity against fleas (*Ctenocephalides felis*), ticks (*Rhipicephalus turanicus*, *Ixodes ricinus*) in addition to preventing flea eggs developing into adult fleas.

Such combination provides an integrated flea control which can be used against infestations with fleas alone or in association with ticks.

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Gavin Hall

Approved 11 January 2025