ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Fipronil Pyriproxyfen Virbac 268 mg/80 mg Spot-on Solution for Large Dogs

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 268 mg/80 mg Spot-on Solution for Large Dogs
Fipronil/Pyriproxyfen

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette contains:

[optional]	Fipronil	Pyriproxyfen
2.68 ml	268 mg	80.4 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1
2.68 ml

4
2.68 ml

24
2.68 ml

60
2.68 ml

5. TARGET SPECIES

Dogs 20-40 kg

6. INDICATION(S)

To be used against infestations with fleas alone or in association with ticks.
Fleas, flea eggs & Ticks

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.

[optional]	Dog	Fipronil	Pyriproxyfen
0.67 ml	2-10 kg	67 mg	20.1 mg
1.34 ml	10-20 kg	134 mg	40.2 mg
2.68 ml	20-40 kg	268 mg	80.4 mg
4.02 ml	40-60 kg	402 mg	120.6 mg

For dogs over 60 kg the appropriate combination of pipettes should be used.
Read the package leaflet before use.
[optional]

8. WITHDRAWAL PERIOD

Withdrawal period: Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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]

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

Disposal: Read the package leaflet.

[optional]

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.

[optional]

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5032

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Fipronil Pyriproxyfen Virbac 268 mg/80 mg Spot-on Solution for Large Dogs

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 268 mg/80 mg Spot-on Solution for Large Dogs
Fipronil/Pyriproxyfen

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette contains:

[optional]	Dog	Fipronil	Pyriproxyfen
0.67 ml	2-10 kg	67 mg	20.1 mg
1.34 ml	10-20 kg	134 mg	40.2 mg
2.68 ml	20-40 kg	268 mg	80.4 mg
4.02 ml	40-60 kg	402 mg	120.6 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs

6. INDICATION(S)

To be used against infestations with fleas alone or in association with ticks.
Fleas, flea eggs & Ticks

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.
For dogs over 60 kg the appropriate combination of pipettes should be used.
Read the package leaflet before use.

[optional]

8. WITHDRAWAL PERIOD

Withdrawal period: Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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]

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

Disposal: read the package leaflet.

[optional]

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.

[optional]

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5032

17. MANUFACTURER'S BATCH NUMBER

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

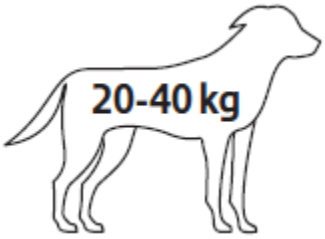
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Fipronil Pyriproxyfen Virbac 268 mg/80 mg Spot-on Solution for Large Dogs

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipronil Pyriproxyfen Virbac 268 mg/80 mg Spot-on Solution for Large Dogs
Fipronil/Pyriproxyfen



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil	268 mg
Pyriproxyfen	80 mg

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

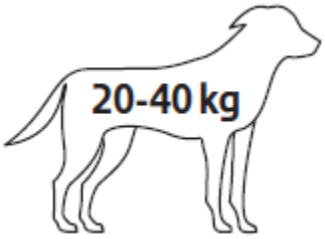
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Fipronil Pyriproxyfen Virbac 268 mg/80 mg Spot-on Solution for Large Dogs

Individual Pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipronil Pyriproxyfen Virbac 268 mg/80 mg Spot-on Solution for Large Dogs
Fipronil/Pyriproxyfen



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil 268 mg
Pyriproxyfen 80 mg

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Fipronil Pyriproxyfen Virbac 67 mg/20 mg spot-on solution for small dogs
Fipronil Pyriproxyfen Virbac 134 mg/40 mg spot-on solution for medium dogs
Fipronil Pyriproxyfen Virbac 268 mg/80 mg spot-on solution for large dogs
Fipronil Pyriproxyfen Virbac 402 mg/120 mg spot-on solution for very large 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 and manufacturer responsible for batch release:
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipronil Pyriproxyfen Virbac 67 mg/20 mg spot-on solution for small dogs
Fipronil Pyriproxyfen Virbac 134 mg/40 mg spot-on solution for medium dogs
Fipronil Pyriproxyfen Virbac 268 mg/80 mg spot-on solution for large dogs
Fipronil Pyriproxyfen Virbac 402 mg/120 mg spot-on solution for very large dogs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each pipette contains:	Active substances		Excipients	
Pipette volume (single dose unit)	Fipronil	Pyriproxyfen	BHA	BHT
0.67 ml	67 mg	20.1 mg	0.134 mg	0.067 mg
1.34 ml	134 mg	40.2 mg	0.268 mg	0.134 mg
2.68 ml	268 mg	80.4 mg	0.536 mg	0.268 mg
4.02 ml	402 mg	120.6 mg	0.804 mg	0.402 mg

Clear, colourless to yellowish solution.

4. INDICATIONS

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 7 weeks.
Prevention of the multiplication of fleas preventing flea eggs developing into adult fleas for 12 weeks after application.
The 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).*
One treatment provides persistent acaricidal efficacy for 2 weeks against *Ixodes ricinus*, and for 4 weeks against *Dermacentor reticulatus* and *Rhipicephalus sanguineus*.
If ticks of some species (*Dermacentor reticulatus*, *Rhipicephalus sanguineus*) 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 known hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

Transient cosmetic effects such as wet appearance or slight scaling may occur at the application site.
According to the accumulated experience on these active ingredients within spot on pharmaceutical forms, transient cutaneous reactions at the application site (squamosis (scaling of the skin), local alopecia (hair loss), pruritus (itchiness), erythema (redness of the skin), skin discolouration) and general pruritus or alopecia may be observed after use. In very rare instances, hypersalivation, reversible neurologic symptoms (hyperesthesia (increased sensitivity to stimuli), depression, nervous symptoms), respiratory signs or vomiting might occur.

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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.
Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

For dogs

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

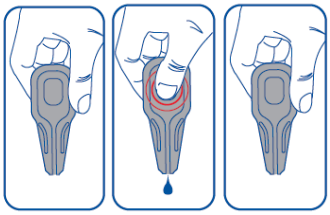
Dosage:

Dog weight	Pipette volume (single dose unit)	Fipronil (mg)	Pyriproxyfen (mg)
2-10 kg	0.67 ml	67	20.1
10-20 kg	1.34 ml	134	40.2
20-40 kg	2.68 ml	268	80.4
40-60 kg	4.02 ml	402	120.6

For dogs over 60 kg the appropriate combination of pipettes should be used.

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 pet's coat on base of the neck before the shoulder blades until the skin is visible. Place the tip of the pipette directly against the skin and squeeze gently several times to empty the contents. If necessary the contents of the pipette can be administered at one or two additional point(s) along the pet's back to avoid run-off or more superficial application to the hair coat, particularly in large dogs.

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



9. ADVICE ON CORRECT ADMINISTRATION

One pipette provides a single treatment, with the possibility to repeat administrations on a monthly basis.
Consult your veterinary surgeon if the product fails to control the flea and tick infestation.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
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.
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.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Shampooing or immersion of the animal in water directly after treatment may reduce the duration of activity. The product remains effective against fleas for 5 weeks when the dog is shampooed at monthly intervals after treatment. If the dog requires shampooing, it is better to do so before treatment.
Water immersion repeated on two occasions post treatment did not affect adulticidal efficacy against fleas nor the efficacy related to the prevention of the development of flea eggs into adult fleas.

The influence of water immersion or shampooing of the dog on the efficacy of the product against ticks has not been evaluated.

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 product.

The product does not prevent ticks from attaching to animals. Transmission of infectious disease by ticks cannot be completely excluded if conditions are unfavourable. Immediate efficacy has been demonstrated against *Ixodes ricinus*, indicating that ticks of this species are likely to be killed within 48 hours of product application. If *Dermacentor reticulatus* or *Rhipicephalus sanguineus* ticks are present when the product is applied, these ticks may not be killed within the first 48 hours.
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 use in animals:

For external use only.
Animals should be weighed accurately prior to treatment.
In absence of safety data, the product should not be used in puppies less than 10 weeks old and/or weighing less than 2 kg.
Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.
Do not apply the product on wounds or damaged skin.

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

The use of the product has not been studied in sick and debilitated dogs.
Consult your veterinary surgeon before using the product if your dog is unwell or currently receiving any other veterinary treatment.
Inform your veterinary surgeon if you are using this product if s/he provides your dog with any other medication.
Seek veterinary advice if the product is accidentally ingested or comes into contact with your animal's eyes.

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

The product may cause neurotoxicity.
The 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 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
Fipronil and pyriproxyfen may adversely affect aquatic organisms. Dogs should be prevented from accessing streams and rivers for 48-hours following treatment.
The 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 shown any evidence of teratogenic or embryotoxic effect. Studies have not been carried out with this product in pregnant and lactating bitches.
Consult your veterinary surgeon before using the product in pregnant or lactating bitches.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with other flea or tick products which are applied directly on to the animal.

Overdose (symptoms, emergency procedures, antidotes):
No serious adverse effects were observed in a safety study in 10-week old puppies 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 reactions (see section 6) may however increase with overdosing, so animals should always be treated with correct pipette size according to bodyweight.

Incompatibilities:
None known.

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 product should be disposed of in accordance with local requirements.

Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty container as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2021

15. 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 sanguineus*, *Dermacentor reticulatus*, *Ixodes ricinus*) in addition to preventing flea eggs developing into adult fleas.

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.

Approved 25 October 2021