ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PERFIKAN 268 mg/2400 mg spot-on solution for large dogs

Box containing 2 individual pipette placed in overblister
Box containing 4 individual pipettes placed in overblister
Box containing 6 individual pipettes placed in overblister

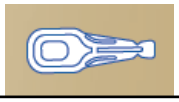
1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PERFIKAN 268 mg/2400 mg spot-on solution for large dogs
Fipronil/Permethrin

Dog 20 – 40 kg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each pipette contains:

	Weight	Fipronil	Permethrin
0.44 ml	1.5-4 kg	26.8 mg	240 mg
1.10 ml	4-10 kg	67 mg	600 mg
2.20 ml	10-20 kg	134 mg	1200 mg
4.40 ml	20-40 kg	268 mg	2400 mg
6.60 ml	40-60 kg	402 mg	3600 mg

Other substances: Butylhydroxyanisole (E320), Butylhydroxytoluene (E321)

Clear yellow solution.

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

2 x 4.40 ml
4 x 4.40 ml
6 x 4.40 ml

5. TARGET SPECIES

Dogs 20-40 kg

6. INDICATION(S)

In dogs, to be used against infestations with fleas and/or ticks when repellent (anti-feeding) activity is also necessary against sand-flies and/or mosquitoes.

Fleas & Ticks + Sand-flies & mosquitoes

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.

Read the package leaflet before use.

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

Store below 30°C.
Keep the blister pack in the outer carton in order to protect from light


+30°C

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

Read the package leaflet for disposal advice.

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

ALFAMED
13ème Rue – L.I.D.
06517 CARROS CEDEX
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 17902/4099

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
PERFIKAN 268 mg/2400 mg spot-on solution for large dogs

Individual pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PERFIKAN 268 mg/2400 mg spot-on solution for large dogs

20-40 kg
Fipronil/Permethrin

[This pictogram may or may not be included without the weight range]

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil	268 mg
Permethrin	2400 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. [this statement will already be mentioned on the overblister which will be first read before its opening to have access to the pipette]

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
PERFIKAN 268 mg/2400 mg spot-on solution for large dogs

Individual overblister (packed in 2 pipette blisters divisible per pipette)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PERFIKAN 268 mg/2400 mg spot-on solution for large dogs

20-40 kg
Fipronil/Permethrin

[This pictogram may or may not be included]

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil	268 mg
Permethrin	2400 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:

Perfikan 26.8 mg/240 mg spot-on solution for very small dogs
Perfikan 67 mg/600 mg spot-on solution for small dogs
Perfikan 134 mg/1200 mg spot-on solution for medium dogs
Perfikan 268 mg/2400 mg spot-on solution for large dogs
Perfikan 402 mg/3600 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:
ALFAMED
13ème Rue – L.I.D.
06517 CARROS CEDEX
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Perfikan 26.8 mg/240 mg spot-on solution for very small dogs
Perfikan 67 mg/600 mg spot-on solution for small dogs
Perfikan 134 mg/1200 mg spot-on solution for medium dogs
Perfikan 268 mg/2400 mg spot-on solution for large dogs
Perfikan 402 mg/3600 mg spot-on solution for very large dogs

Fipronil/Permethrin

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

Each pipette contains:

	Fipronil	Permethrin	Butylhydroxyanisole (E320)	Butylhydroxytoluene (E321)	Excipients*
Perfikan (UK, PT) / CANIGUARD DUO (ES, IT) for very small dogs	26.84 mg	239.8 mg	0.088 mg	0.044 mg	QSP 0.44 ml
Perfikan (UK, PT) / CANIGUARD DUO (ES, IT) for small dogs	67.1 mg	599.5 mg	0.22 mg	0.11 mg	QSP 1.1 ml
Perfikan (UK, PT) / CANIGUARD	134.2 mg	1199.0 mg	0.44 mg	0.22 mg	QSP 2.2 ml

DUO (ES, IT) for medium dogs					
Perfikan (UK, PT) / CANIGUARD DUO (ES, IT) for large dogs	268.4 mg	2398.0 mg	0.88 mg	0.44 mg	QSP 4.4 ml
Perfikan (UK, PT) / CANIGUARD DUO (ES, IT) for very large dogs	402.6 mg	3597.0 mg	1.32 mg	0.66 mg	QSP 6.6 ml

*** Other ingredients:** Benzyl alcohol, Diethylene glycol monoethyl ether

Clear yellow solution.

4. INDICATION(S)

In dogs, to be used against infestations with fleas and/or ticks when repellent (anti-feeding) activity is also necessary against sand-flies and/or mosquitoes.

Fleas:
Treatment and prevention of infestations by fleas *(Ctenocephalides felis).* Fleas on dogs are killed within 24 hours following treatment. One treatment provides persistent efficacy against new infestations with adult fleas for four weeks. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this condition has previously been diagnosed by a veterinarian.

Ticks:
Treatment of infestations with *Ixodes ricinus* ticks.
One application provides four weeks persistent acaricidal efficacy against tick infestations (*Ixodes ricinus*, *Dermacentor reticulatus* and *Rhipicephalus sanguineus*).
If ticks of some species (*Dermacentor reticulatus* and *Rhipicephalus sanguineus*) are present at the time of application, not all the ticks may be killed within 48 hours.

Sand-flies and mosquitoes:
One treatment provides repellent (anti-feeding) activity against sand-flies (*Phlebotomus perniciosus*) and against mosquitoes (*Culex pipiens, Aedes aegypti*) for four weeks.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substances or to any of the other ingredients.
Do not use on rabbits and cats as adverse reactions and even death can occur (see also section 12i Special precautions for use in animals).
Do not use on sick (e.g. systemic diseases, fever…) or convalescent animals.

6. ADVERSE REACTIONS

Among the suspected adverse reactions, transient cutaneous reactions on the application site (pruritus, erythema) and general pruritus have been reported in few dogs after use. Exceptionally, hyperactivity or vomiting has been observed.
If licking occurs, transient hypersalivation may be observed.

7. TARGET SPECIES

Dogs

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

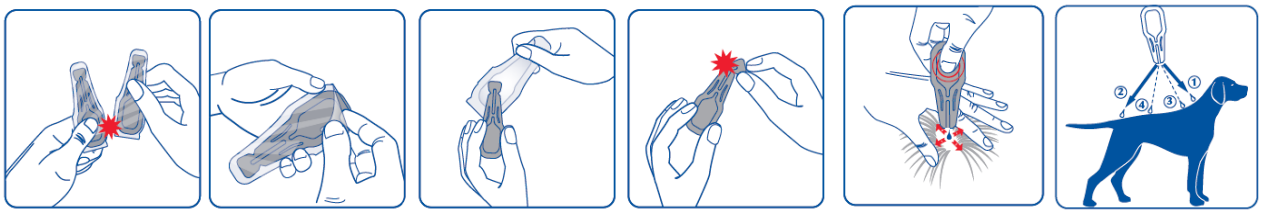
Spot-on use.

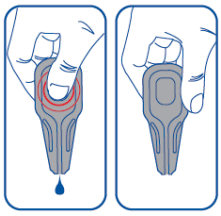
Dosage:
The recommended minimum dose is 6.7 mg fipronil /kg b.w.and 60 mg permethrin/kg b.w.

Dog weight	Fipronil (mg)	Permethrin (mg)
1.5-4 kg	26.8	240
4-10 kg	67	600
10-20 kg	134	1200
20-40 kg	268	2400
40-60 kg	402	3600

For dogs > 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 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 at two to four different points, depending on body weight, along the pet's back from the shoulder to the base of the tail.
As a guide, dogs under 20 kg should have the product applied in two spots, whereas those over 20 kg should receive the product in 2-4 spots.



Drop stop system. 

9. ADVICE ON CORRECT ADMINISTRATION

Treatment schedule:
The use of the product should be based on a confirmed infestation or risk of infestation, with fleas and/or ticks when repellent (anti-feeding) activity is also necessary against sand-flies and/or mosquitoes.
Depending on the ectoparasite challenge the responsible veterinary surgeon may recommend repeating the treatment. The interval between two treatments should be at least 4 weeks (see also section Overdose).

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 30°C.
Store in the original carton in order to protect from light.

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

12. SPECIAL WARNINGS

Special warnings for each target species:

The veterinary medicinal product remains effective after exposure to sunlight or if the animal becomes wet after rain.
Avoid frequent swimming or shampooing of treated dogs as this may adversely affect maintenance of product effectiveness.

A dog with fleas may show an allergic reaction to the flea saliva called Flea Allergy Dermatitis (FAD). If your dog has inflamed skin, is itchy and bites, scratches excessively and is restless and uncomfortable, you should seek the advice of a veterinarian to diagnose if your dog suffers from FAD.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. 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.

There may be an attachment of single ticks or bites by single sand-flies or mosquitoes. For this reason, the transmission of infectious diseases by these parasites cannot be excluded if conditions are unfavourable.

Studies have shown anti-feeding effect of four weeks for sand-flies and mosquitoes. Therefore, for short-term travel (less than 4 weeks) to endemic areas it is recommended to apply the treatment immediately before expected exposure. For longer-term exposure (e.g. animals living in endemic areas or travel duration longer than 4 weeks), the treatment schedule should be based on local epidemiological information.

i) Special precautions for use in animals:

Animals should be weighed accurately prior to treatment.
The safety of the product has not been established in dogs younger than 12 weeks of age or in dogs weighing less than 1.5 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.

This product is extremely poisonous to cats and could be fatal. In case of accidental dermal exposure, wash the cat with shampoo or soap, and seek veterinary advice rapidly. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. In case of exposure of this type, seek veterinary advice immediately if this occurs.
Do not use on rabbits and cats.

ii) 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. 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. Therefore, avoid contact between the product and the mouth or eyes including hand-to-mouth and hand-to-eye contacts. In the event of accidental contact between the product and eyes, 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 contact with the skin. Should the product come into contact with skin, wash the contacted area immediately with soap and water.
Wash hands thoroughly after use.
Do not eat, drink or smoke while handling the veterinary medicinal product.
Keep strictly out of reach and sight of children.

People with a known hypersensitivity (allergy) to fipronil, permethrin or any of the other ingredients should avoid contact with the veterinary medicinal product, which, on very rare occasions, can cause respiratory irritation and dermal reactions in certain individuals.
Treated animals should not be handled or played with until the application site is dry and for about 12 hours after treatment. It is therefore recommended to treat the animals in the early evening or late afternoon in order to minimise contact with the treated animal. On the day of treatment, treated animals should not be permitted to sleep with their owner, especially children.
Keep the stored pipettes in the original packaging. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately in a proper way.

For animal treatment only.

iii) Other precautions

Fipronil and permethrin may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.
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 permethrin have not shown any evidence of harmful effect on the embryo or the foetus. However no studies have been carried out with this product in pregnant or lactating bitches. Use during pregnancy or lactation must therefore be in accordance with professional veterinary advice and a benefit/risk assessment.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
Safety has been demonstrated with up to 5 times the maximum recommended dose in healthy 12-week old puppies treated 3 times at intervals of 3 weeks.
The risk of experiencing adverse reactions (see section ‘POSSIBLE SIDE EFFECTS IN YOUR PET’) 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

15. OTHER INFORMATION

*****Only for those countries where expanded text is proposed:*****

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. Fipronil and its metabolite fipronil sulfone act at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA) as well as desensitising (D) and non-desensitising (N) channels gated by glutamate (Glu, unique invertebrate ligand-gated chloride channels), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acari.

Permethrin belongs to the type I class of pyrethroid acaricides and insecticides and also acts as repellent. Pyrethroids affect the voltage-gated sodium channels in vertebrates and non-vertebrates. Pyrethroids are so called “open channel blockers” affecting the sodium channel by slowing both the activation and the inactivation properties thus leading to hyperexcitability and death of the parasite.

The product provides an immediate and persistent insecticidal activity against fleas (*Ctenocephalides felis*), immediate acaricidal activity against *Ixodes ricinus* ticks, persistent acaricidal activity against ticks (*Rhipicephalus sanguineus*, *Dermacentor reticulatus* and *Ixodes ricinus*) and repellent (anti-feeding) activity against sand-flies (*Phlebotomus perniciosus*) and mosquitoes (*Culex pipiens, Aedes aegypti*).

When applied to dogs at least 2 days prior to tick exposure, the product was experimentally shown to indirectly reduce the risk of *Babesia canis canis* transmission from infected ticks *Dermacentor reticulatus* until 28 days after application, thereby reducing the risk of canine babesiosis in treated dogs.

Boxes of 2, 4 or 6 pipettes.
Not all pack sizes may be marketed.

Approved: 14 November 2017