ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 1 individual pipettes placed in overblister
Box containing 2 individual pipettes 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

Fiproxile 268 mg/2400 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4.4 ml pipette contains:

Fipronil	268.4 mg
Permethrin	2398.0 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

Dogs 20-40 kg

5. INDICATIONS

For products not subject to veterinary prescription

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 veterinary medicinal 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 or Rhipicephalus sanguineus) are present at the time of application, not all 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.

6. ROUTES OF ADMINISTRATION

Spot-on solution.

[optional]

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store below 30°C.
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.

[optional]

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

ALFAMED

14. MARKETING AUTHORISATION NUMBERS

Vm 17902/3023

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Individual pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiproxile

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

268 mg/2400 mg
20-40 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiproxile

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

268 mg/2400 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

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

2. Composition

Each pipette contains:

	Fipronil	Permethrin	Butylhydroxyanisole (E320)	Butylhydroxytoluene (E321)	Excipients*
Fiproxile / Perfikan / Fiprotix / Fipratix / Itch Poof very small dogs	26.84 mg	239.8 mg	0.088 mg	0.044 mg	QSP 0.44 ml
Fiproxile / Perfikan / Fiprotix / Fipratix / Itch Poof small dogs	67.1 mg	599.5 mg	0.22 mg	0.11 mg	QSP 1.1 ml
Fiproxile / Perfikan / Fiprotix / Fipratix / Itch Poof medium dogs	134.2 mg	1199.0 mg	0.44 mg	0.22 mg	QSP 2.2 ml
Fiproxile / Perfikan / Fiprotix / Fipratix / Itch Poof large dogs	268.4 mg	2398.0 mg	0.88 mg	0.44 mg	QSP 4.4 ml
Fiproxile / Perfikan / Fiprotix / Fipratix / Itch Poof very large dogs	402.6 mg	3597.0 mg	1.32 mg	0.66 mg	QSP 6.6 ml

Clear yellow solution.

3. Target species

Dogs

4. Indications for use

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 veterinary medicinal 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* or *Rhipicephalus sanguineus*) are present at the time of application, not all 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 cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in rabbits and cats as adverse reactions and even death can occur (see also section “Special precautions for safe use in the target species”).
Do not use in sick (e.g. systemic diseases, fever…) or convalescent animals.

6. Special warnings

Special warnings:

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 the veterinary medicinal 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.

Special precautions for safe use in the target species:

Animals should be weighed accurately prior to treatment.
The safety of the veterinary medicinal 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 veterinary medicinal product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. 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 veterinary medicinal 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 veterinary medicinal product. In case of exposure of this type, seek veterinary advice immediately if this occurs.
Do not use on rabbits and cats.

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. In case 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. Therefore, avoid contact between the veterinary medicinal product and the mouth or eyes including hand-to-mouth and hand-to-eye contacts. In case of accidental contact between the veterinary medicinal 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 veterinary medicinal 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.
FPeople with known hypersensitivity (allergy) to fipronil, permethrin or any of the excipients should avoid contact with the veterinary medicinal product, which, on very rare occasions, can cause respiratory irritation and dermal reactions in certain individuals.
Should symptoms occur, seek medical advice immediately and show the package leaflet or the label to the physician.
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.

Special precautions for the protection of the environment:

Fipronil and permethrin 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. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

Laboratory studies in dogs using fipronil and permethrin have not produced any evidence of teratogenic or embryotoxic effects.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in bitches.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose:

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 'Adverse events') may however increase with overdosing, so animals should always be treated with correct pipette size according to bodyweight.

Major incompatibilities:

Not applicable.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site Pruritus (itching)[1], Application site Erythema (redness)[1], Application site Alopecia (hair loss)[1] Generalised Itching Hyperactivity, Agitation Muscle tremor, Convulsion, Ataxia (incoordination) Lethargy Vomiting, Hypersalivation[1,2]

[1]Transient
[2]If licking occurs

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 its local representative 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

For external use only.
Spot-on use.

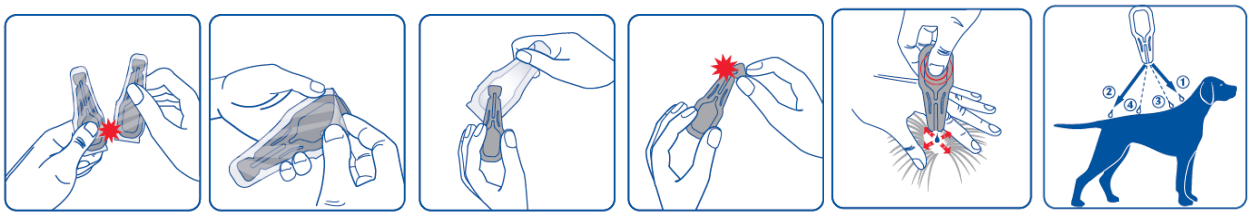
Dosage:
The recommended minimum dose is 6.7 mg fipronil /kg b.w.and 60 mg permethrin/kg b.w.

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

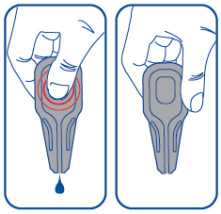
>40-60 kg	402	3600

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 veterinary medicinal product applied in two spots, whereas those over 20 kg should receive the veterinary medicinal product in 2-4 spots.



Drop stop system.



9. Advice on correct administration

Treatment schedule:
The use of the veterinary medicinal 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 periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 30 °C.
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 label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: Use immediately.

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 fipronil and permethrin may be dangerous for fish and other aquatic organisms.

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.

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

14. Marketing authorisation numbers and pack sizes

Vm 17902/3023

Boxes of 1, 2, 4 or 6 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 events:

ALFAMED
13ème rue LID
06517 Carros
France

Local representatives and contact details to report suspected adverse events:

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

17. 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 veterinary medicinal 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 veterinary medicinal 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.

Gavin Hall

Approved: 02 December 2025