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

VETFLEA 268 mg Spot-on solution for large dogs
Fipronil

2. STATEMENT OF ACTIVE SUBSTANCE

One 2.68 ml pipette contains 268 mg of fipronil.

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

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

5. TARGET SPECIES

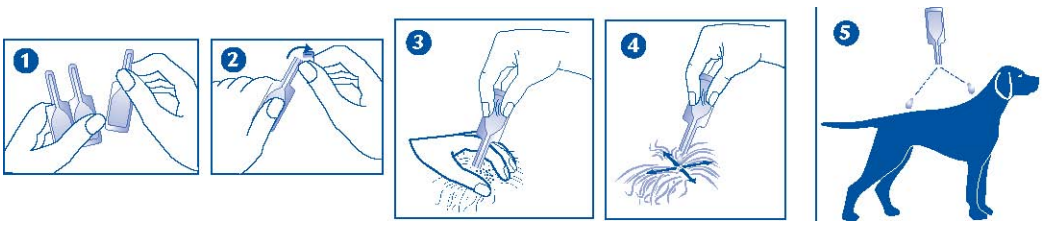
Dogs.

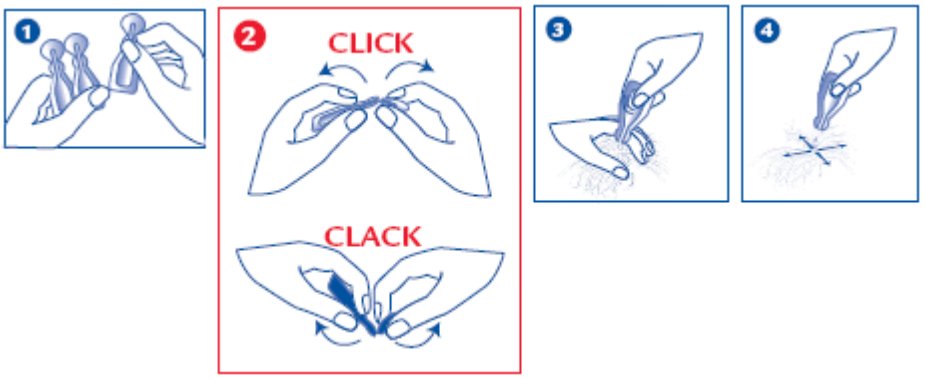
6. INDICATIONS

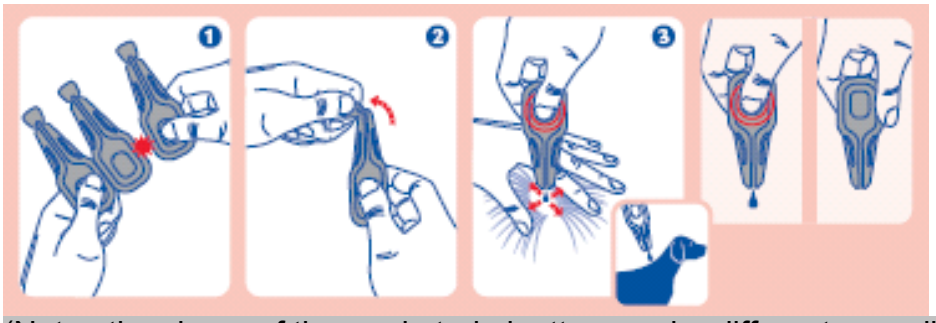
7. METHOD AND ROUTE OF ADMINISTRATION

External use only.
1 pipette of 2.68 ml per dog weighing over 20 kg and up to 40 kg bodyweight.

Read the package leaflet before use.







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

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS

User warnings: Please read the package leaflet before use.

10. EXPIRY DATE

EXP :{month/year}

11. SPECIAL STORAGE CONDITIONS

Store below 30°C. Store in a dry place. Store in the original package.

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

Read the package leaflet before use.

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

Vm 17902/4023

17. MANUFACTURER’S BATCH NUMBER

Batch : {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1 blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETFLEA L

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSE

268 mg

3. ROUTE(S) OF ADMINISTRATION

(reference is made to the dog logo and drop in section 1)

4. EXPIRY DATE

EXP : {month/year}

5. BATCH NUMBER

Batch : {number}

6. MARKETING AUTHORISATION HOLDER

ALFAMED

MINIMUM PARTICULARS TO APPEAR ON PIPETTES

1 pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETFLEA L

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSE

268 mg

3. ROUTE(S) OF ADMINISTRATION

(reference is made to the dog logo and drop in section 1)

4. EXPIRY DATE

EXP : {month/year}

5. BATCH NUMBER

Batch : {number}

6. MARKETING AUTHORISATION HOLDER

ALFAMED

B. PACKAGE LEAFLET

PACKAGE LEAFLET

VETFLEA 100 mg/ml Spot-on solution for small, medium, large and 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 :
Alfamed
13ème Rue - L.I.D
06517 Carros Cedex
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETFLEA 100 mg/ml Spot-on solution for small, medium, large and very large dogs
Fipronil

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active substance:
Each ml contains 100 mg fipronil.

VETFLEA (UK) delivers the following amount:

	Unit dose	Fipronil
for small dogs (S)	0.67 ml	67 mg
for medium dogs (M)	1.34 ml	134 mg
for large dogs (L)	2.68 ml	268 mg
for very large dogs (XL)	4.02 ml	402 mg

Excipients:

	Butyhydroxyanisole E320	Butylhydroxytoluene E321
for small dogs (S)	0.134 mg/pipette	0.067 mg/pipette
for medium dogs (M)	0.268 mg/pipette	0.134 mg/pipette
for large dogs (L)	0.536 mg/pipette	0.268 mg/pipette
for very large dogs (XL)	0.804 mg/pipette	0.402 mg/pipette

4. INDICATIONS

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

Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. The 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 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 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. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
Very rarely, transient cutaneous reactions at the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Anorexia, hypersalivation, lethargy, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms), vomiting or respiratory symptoms have also been observed very rarely after use.

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 leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE 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,

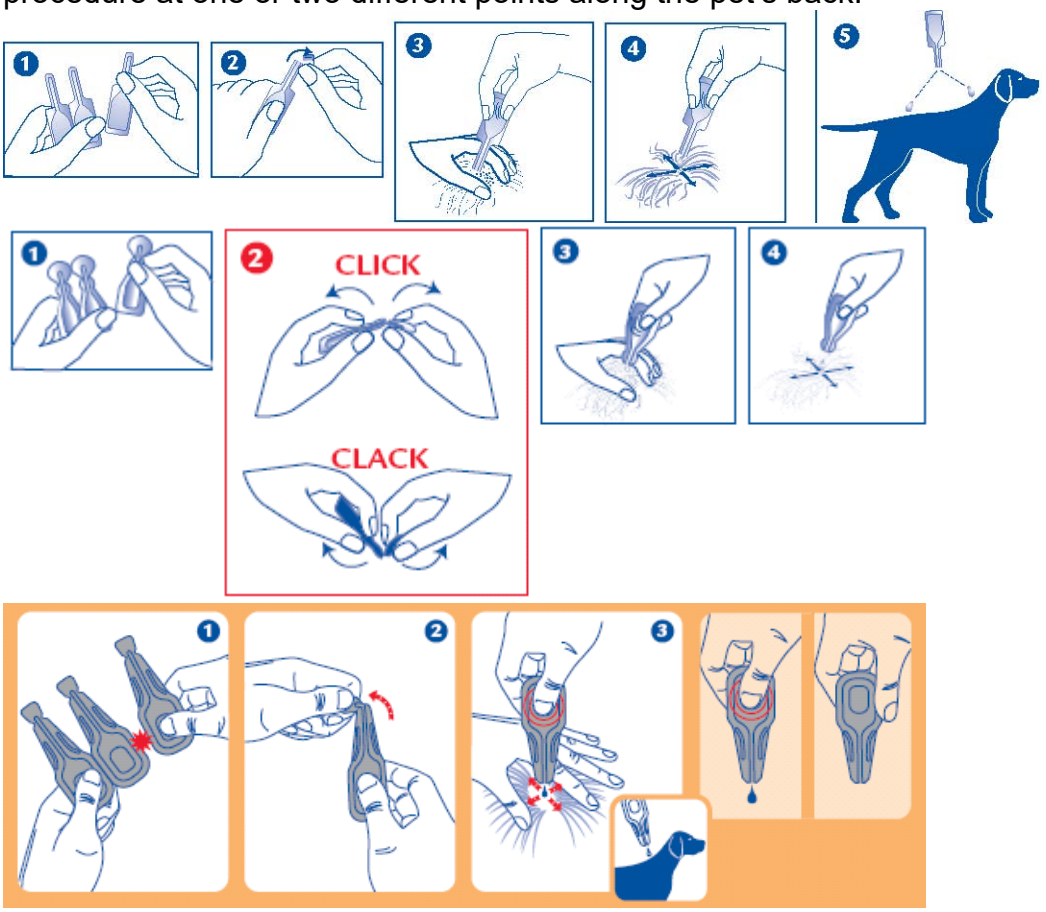
* 1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight
* 1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight
* 1 pipette of 2.68 ml per dog weighing over 20 kg and up to 40 kg bodyweight
* 1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight

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

Method of administration:

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.)

It is important to make sure that the 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 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 PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30°C. Store in a dry place. Store in the original package.
Do not use after the expiry date stated on the carton and pipette after “EXP”.

12. SPECIAL WARNINGS

Special warnings for each target species
Shampooing an hour prior to treatment does not affect the efficacy of the product against fleas.
Bathing/immersion in water within two days after application of the product should be avoided. Weekly immersion in water for one minute reduces the period of persistent insecticidal efficacy against fleas by one week.

The 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 use in animals
Animals should be weighed accurately prior to treatment.

Avoid contact with the animal’s eyes. In the case of accidental eye contact, immediately rinse the eyes with clean water.

It is important to make sure that the 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 product on wounds or damaged skin.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This 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 rinse the eyes with clean 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 a 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.

Other precautions
Fipronil 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.

Use during pregnancy and lactation
Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effect. Studies have not been carried out with this product in pregnant and lactating bitches. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

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 products should be disposed of in accordance with local requirements. Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Pack sizes :
Boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

Not all pack sizes may be marketed.

Approved: 28 March 2018