

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alfamed Fipronil 402 mg spot-on solution for very large dogs (UK/NI)  
Fipralone 402 mg spot-on solution for very large dogs (IT)  
Fipromedic 402 mg spot-on solution for very large dogs (FR)  
Flea Free XL 402 mg spot-on solution for very large dogs (NL)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.02 ml pipette contains:

### Active substances:

Fipronil 402 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylhydroxyanisole (E320)	0.804 mg
Butylhydroxytoluene (E321)	0.402 mg
Benzyl alcohol	
Diethylene glycol monoethyl ether	

Clear, colourless to yellow spot-on solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs.

### 3.2 Indications for use for each target species

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

Insecticidal efficacy against new infestations with adult fleas persists for up to 8 weeks.

The veterinary medicinal 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 veterinary medicinal product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

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.

### 3.3 Contraindications

Do not use in puppies less than 2 months old and/or weighing less than 2 kg in the absence of available data.

Do not use in sick (e.g. systemic diseases, fever...) or convalescent animals.

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

This veterinary medicinal 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 the excipients.

### **3.4 Special warnings**

Shampooing an hour prior to treatment does not affect the efficacy of the veterinary medicinal product against fleas.

Bathing/immersion in water within two days after application of the veterinary medicinal product should be avoided. Weekly immersion in water for one minute reduces the period of persistent insecticidal efficacy against fleas by one week and therefore it is advisable to avoid frequent swimming and shampooing.

The veterinary medicinal 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.

### **3.5 Special precautions for use**

#### Special precautions for safe use in the target species:

Animals should be weighed accurately prior to treatment.

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

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

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

This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the veterinary medicinal product and the mouth or eyes should be avoided.

In case of accidental eye contact, immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice immediately 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 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.

#### Special precautions for the protection of the environment:

Fipronil 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.

### 3.6 Adverse events

Dogs:

Very rare ( $<1$ animal / 10,000 animals treated, including isolated reports):	Application site skin discolouration <sup>1</sup> , Application site alopecia <sup>1</sup> , Application site pruritus <sup>1</sup> , Application site erythema <sup>1</sup> Generalised itching, Alopecia general Vomiting, Hypersalivation <sup>2</sup> Hyperesthesia <sup>3</sup> , central nervous system depression <sup>3</sup> , Neurological symptoms <sup>3</sup> Respiratory tract disorders
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<sup>1</sup>Transient.

<sup>2</sup> Can be observed if licking occurs (in which case the hypersalivation is transient and mainly due to the nature of the carrier), or without any licking.

<sup>3</sup>Reversible.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Laboratory studies in dogs have not produced any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this veterinary medicinal product in pregnant and lactating bitches. Use only according to the benefit-risk assessment by the responsible veterinarian.

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

Route of administration and dosage:

Spot-on use.

External use only.

Administer by topical application to the skin according to the bodyweight as follows:

1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight.

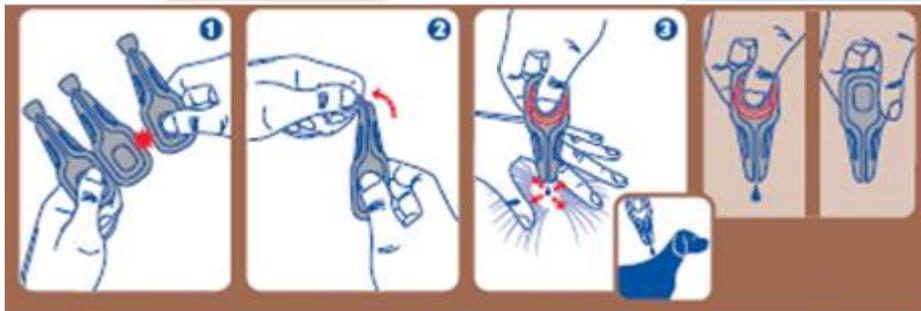
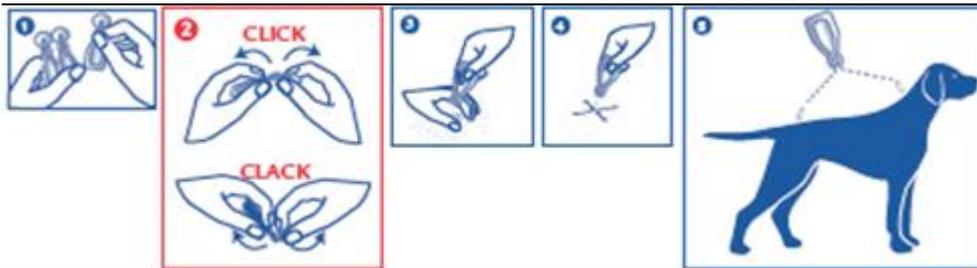
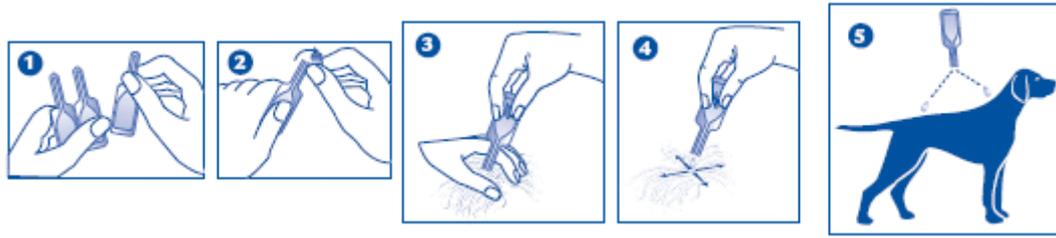
For dogs over 60 kg use two pipettes of 2.68 ml.

Method of administration:

*Thermoformed pipettes:*

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.

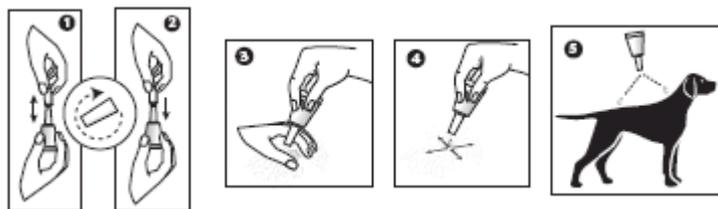


(Note : the shape of the marketed pipettes can be different as well as the pictures on the marketed boxes/package leaflets.)

*Polypropylene pipettes:*

Remove the pipette from the blister packaging. Hold the pipette in an upright position, twist and pull the cap off. Turn the cap around and place the other end of the cap back on the pipette. Twist the cap to break the seal, then remove the cap from the pipette.

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 points along the pet's back.



It is important to make sure that the veterinary medicinal 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 veterinary medicinal 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.

#### 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.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

No adverse effects were observed in target animal safety studies in 2 month-old puppies, growing dogs and dogs weighing about 2 kg treated with the therapeutic dose on five consecutive days. The risk of adverse effects (see section 3.6) may increase in cases of overdose.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

### **3.12 Withdrawal periods**

Not applicable.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code: QP53AX15**

### **4.2 Pharmacodynamics**

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by inhibiting the GABA complex, binding to the chloride channel and 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 acarids.

Fipronil exhibits an insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp), ticks (*Rhipicephalus* spp, *Dermacentor* spp, *Ixodes* spp including *Ixodes ricinus*) in the dog.

Fleas will be killed within 24 h. Ticks will usually be killed within 48 h after contact with Fipronil, however if ticks of some species (*Rhipicephalus sanguineus* and *Ixodes ricinus*) are already present

when the veterinary medicinal product is applied, all of the ticks may not be killed within the first 48 hours.

### **4.3 Pharmacokinetics**

Fipronil is mainly metabolised to its sulfone derivative (RM1602), which also possesses insecticidal and acaricidal properties. The concentrations of fipronil on the hair decrease with time.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

None known.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale:

Thermoformed pipette: 3 years

Polypropylene pipette: 2 years

### **5.3 Special precautions for storage**

Store below 30°C.

Store in a dry place.

Store in the original package.

Do not remove from blister until required for use.

### **5.4 Nature and composition of immediate packaging**

*Thermoformed pipettes:* White or transparent multi-layer plastic single-dose pipettes containing an extractible volume of 4.02 ml.

The internal layers in contact with the veterinary medicinal product are made of polyacrylonitrile-methacrylate or polyethylene-ethylene vinyl alcohol-polyethylene. The white or transparent external complex is composed of polypropylene/ cyclic olefine copolymer/ polypropylene.

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

The boxes contain pipettes either with or without an individual blister for each pipette.

*Polypropylene pipettes:* White polypropylene single-dose pipettes containing an extractible volume of 4.02 ml packaged in uncoloured plastic blister composed of polypropylene/cyclic olefine copolymer / polypropylene closed by heat sealing with a thermosealable lacquered aluminium foil and placed in a carton box or blister card.

Blister cards or boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and 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 applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

ALFAMED

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**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

Alfamed fipronil (UK/NI) / Fipralone (IT) / Fipromedic (FR)/ Flea Free XL (NL)  
402 mg spot-on solution

### 2. STATEMENT OF ACTIVE SUBSTANCES

Each 4.02 ml pipette contains:  
Fipronil 402 mg

### 3. PACKAGE SIZE

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

### 4. TARGET SPECIES

Very Large dogs > 40-60 kg

### 5. INDICATIONS

For products not subject to veterinary prescription.

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

Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. The veterinary medicinal 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 veterinary medicinal product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week. 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.

### 6. ROUTES OF ADMINISTRATION

Spot-on use.  
External use only.



[Optional]

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

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

**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.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

ALFAMED

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

[QR code]

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**1 blister**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fipralone (IT)  
Alfamed Fipronil (UK/NI)  
Fipromedic (FR)  
Flea Free XL (NL)



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

402 mg  
> 40-60 kg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**1 pipette**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fipralone (IT)  
Alfamed Fipronil (UK/NI)  
Fipromedic (FR)  
Flea Free XL (NL)



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

402 mg  
> 40-60 kg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Alfamed Fipronil (UK/NL) / Fipralone (IT) / Fipromedic (FR) / Flea Free S/M/L/XL (NL)  
100 mg/ml spot-on solution for small, medium, large and very large dogs

### 2. Composition

#### Active substances:

Each ml contains 100 mg fipronil.

Each pipette delivers the following amount:

	Unit dose	Fipronil
for small dogs	0.67 ml	67 mg
for medium dogs	1.34 ml	134 mg
for large dogs	2.68 ml	268 mg
for very large dogs	4.02 ml	402 mg

#### Excipients:

	Butyhydroxyanisole E320	Butylhydroxytoluene E321
for small dogs	0.134 mg/pipette	0.067 mg/pipette
for medium dogs	0.268 mg/pipette	0.134 mg/pipette
for large dogs	0.536 mg/pipette	0.268 mg/pipette
for very large dogs	0.804 mg/pipette	0.402 mg/pipette

Clear, colourless to yellow spot-on solution.

### 3. Target species

Dogs.

### 4. Indications for use

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

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

The veterinary medicinal 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 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.

### 5. Contraindications

Do not use in puppies less than 2 months old and/or weighing less than 2 kg in the absence of available data.

Do not use in sick (e.g. systemic diseases, fever...) or convalescent animals.

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

This veterinary medicinal 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 the excipients.

## **6. Special warnings**

### Special warnings:

Shampooing an hour prior to treatment does not affect the efficacy of the veterinary medicinal product against fleas.

Bathing/immersion in water within two days after application of the veterinary medicinal product should be avoided. Weekly immersion in water for one minute reduces the period of persistent insecticidal efficacy against fleas by one week and therefore it is advisable to avoid frequent swimming and shampooing.

The veterinary medicinal 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 safe use in the target species:

Animals should be weighed accurately prior to treatment.

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

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

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

This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the veterinary medicinal product and the mouth or eyes should be avoided.

In case of accidental eye contact, immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice immediately 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 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.

Special precautions for the protection of the environment:

Fipronil 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.

Pregnancy and lactation:

Laboratory studies in dogs have not produced any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this veterinary medicinal product in pregnant and lactating bitches. Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose:

No adverse effects were observed in target animal safety studies in 2 month-old puppies, growing dogs and dogs weighing about 2 kg treated with the therapeutic dose on five consecutive days. The risk of adverse effects (see section “Adverse events”) may increase in cases of overdose.

**7. Adverse events**

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site skin discolouration <sup>1</sup> , Application site alopecia (hair loss) <sup>1</sup> , Application site pruritus (itching) <sup>1</sup> , Application site erythema (reddening) <sup>1</sup> Generalised itching, Alopecia general Vomiting, Hypersalivation (increased salivation) <sup>2</sup> Hyperesthesia (increased sensitivity to stimuli) <sup>3</sup> , central nervous system depression <sup>3</sup> , Neurological symptoms <sup>3</sup> Respiratory tract disorders

<sup>1</sup>Transient.

<sup>2</sup>Can be observed if licking occurs (in which case the hypersalivation is transient and mainly due to the nature of the carrier), or without any licking

<sup>3</sup>Reversible.

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: {national system details}

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

Route of administration and dosage:

Spot-on use.

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

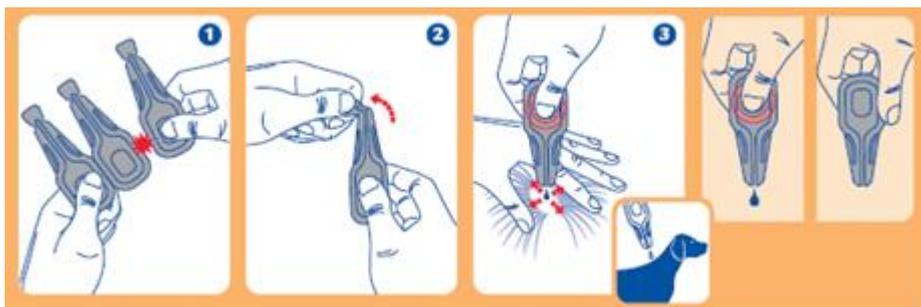
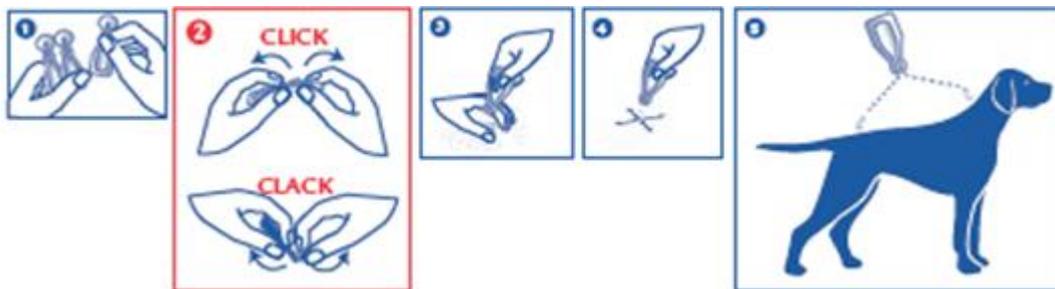
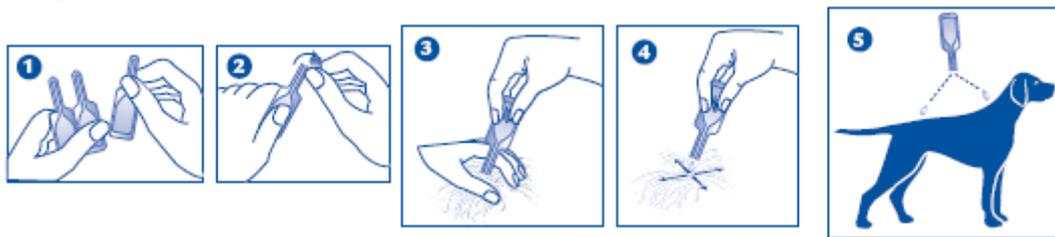
For dogs over 60 kg use two pipettes of 2.68 ml.

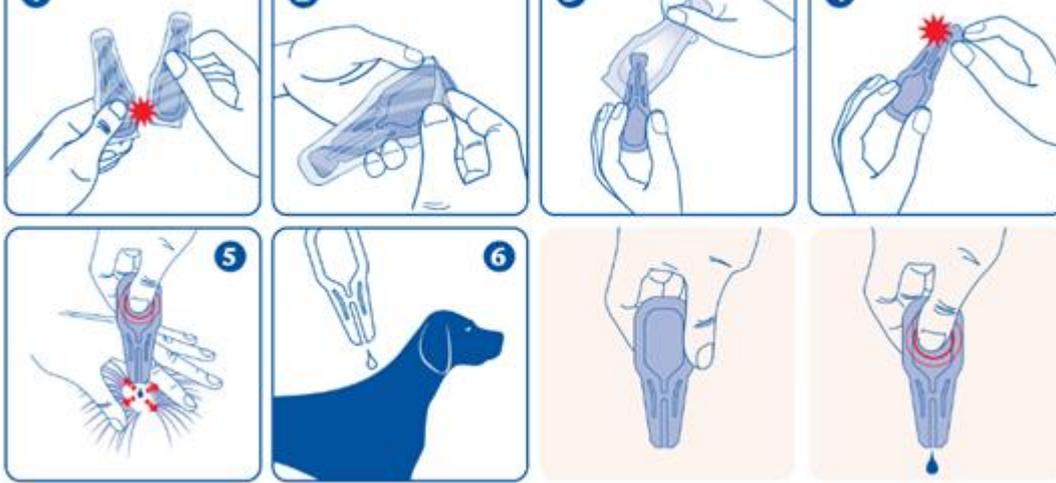
Method of administration:

*Thermoformed pipettes:*

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.



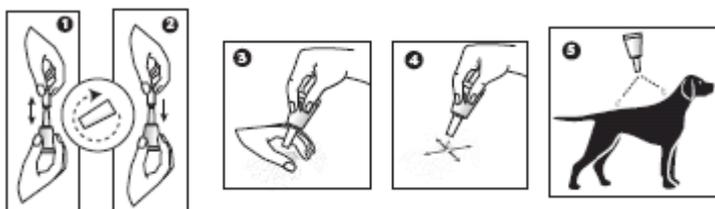


(Note : the shape of the marketed pipettes can be different as well as the pictures on the marketed boxes/package leaflets.)

*Polypropylene pipettes:*

Remove the pipette from the blister packaging. Hold the pipette in an upright position, twist and pull the cap off. Turn the cap around and place the other end of the cap back on the pipette. Twist the cap to break the seal, then remove the cap from the pipette.

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 points along the pet’s back.



It is important to make sure that the veterinary medicinal 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 veterinary medicinal 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 periods**

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 remove from blister until required for use.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and pipette 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.

This veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and 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 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 not subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

Pack sizes:

*Thermoformed pipettes*: boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

*Polypropylene pipettes*: blister cards or boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

Not all pack sizes may be marketed.

## **15. Date on which the package leaflet was last revised**

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

## **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

ALFAMED  
13<sup>eme</sup> 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.

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[QR code]