

## A. LABELLING

### PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

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

Amflee 134 mg spot-on solution

#### 2. STATEMENT OF ACTIVE SUBSTANCES

Each 1.34 ml pipette contains:

fipronil 134 mg

#### 3. PACKAGE SIZE

1 x 1.34 ml  
3 x 1.34 ml  
6 x 1.34 ml  
10 x 1.34 ml  
20 x 1.34 ml  
30 x 1.34 ml

#### 4. TARGET SPECIES

Dogs (>10 kg ≤ 20 kg)



#### 5. INDICATIONS

Treatment of fleas, ticks and lice.



*Ixodida*



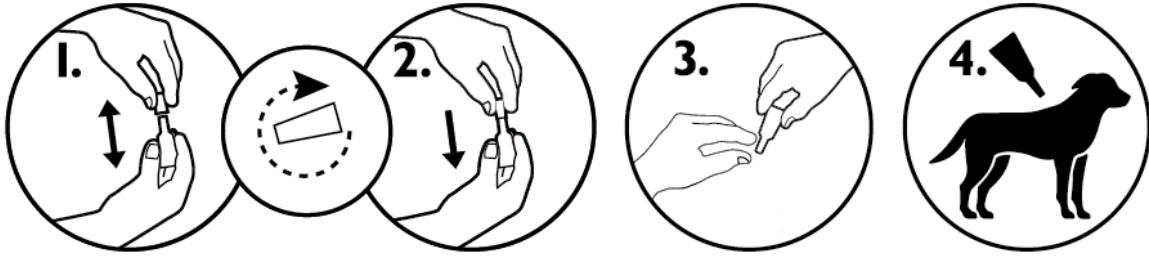
*Ctenocephalides felis*



*Trichodectes canis*

#### 6. ROUTES OF ADMINISTRATION

Spot-on use.



**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

Store in the original container in order to protect from light and moisture. Do not remove from bag until required for use.  
The product should be maintained at room temperature (above 14° C) for approximately one hour prior to administration.

**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**

KRKA, d.d., Novo mesto

**14. MARKETING AUTHORISATION NUMBERS**

Vm 01656/4088

**15. BATCH NUMBER**

Lot {number}

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

**{BAG}**

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

Amflee



>10 kg ≤ 20 kg

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

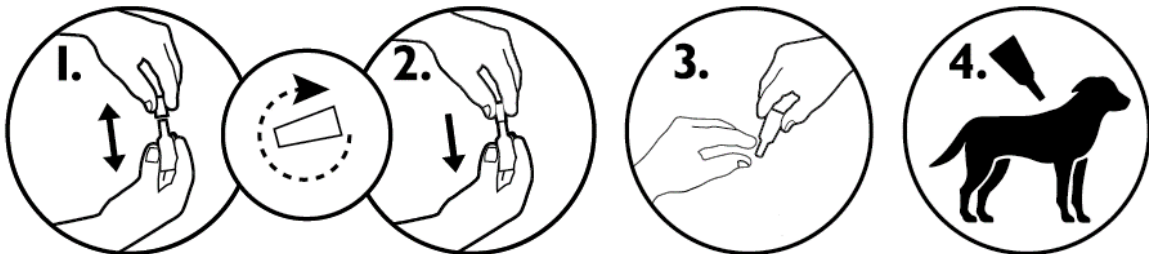
fipronil 134 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}



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

{PIPETTE}

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

Amflee



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

>10 kg ≤ 20 kg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Amflee 67 mg spot-on solution for small dogs  
Amflee 134 mg spot-on solution for medium dogs  
Amflee 268 mg spot-on solution for large dogs  
Amflee 402 mg spot-on solution for extra large dogs

### 2. Composition

Each 0.67 ml pipette contains:

**Active substance:**

Fipronil 67 mg

**Excipients:**

Butylhydroxyanisole (E320) 0.134 mg  
Butylhydroxytoluene (E321) 0.067 mg  
Dimethyl sulfoxide to 0.67 ml

Each 1.34 ml pipette contains:

**Active substance:**

Fipronil 134 mg

**Excipients:**

Butylhydroxyanisole (E320) 0.27 mg  
Butylhydroxytoluene (E321) 0.13 mg  
Dimethyl sulfoxide to 1.34 ml

Each 2.68 ml pipette contains:

**Active substance:**

Fipronil 268 mg

**Excipients:**

Butylhydroxyanisole (E320) 0.54 mg  
Butylhydroxytoluene (E321) 0.27 mg  
Dimethyl sulfoxide to 2.68 ml

Each 4.02 ml pipette contains:

**Active substance:**

Fipronil 402 mg

**Excipients:**

Butylhydroxyanisole (E320) 0.80 mg  
Butylhydroxytoluene (E321) 0.40 mg  
Dimethyl sulfoxide to 4.02 ml

Light yellow to yellow, clear liquid.

### 3. Target species

Dogs >2 kg ≤ 10 kg

Dogs >10 kg ≤ 20 kg

Dogs >20 kg ≤ 40 kg

Dogs > 40 kg



### 4. Indications for use

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

For treatment of *Trichodectes canis* biting lice infestations on dogs. Most lice are killed within 2 days.

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 3 weeks against *Ixodes ricinus* and up to 4 weeks against *Rhipicephalus sanguineus* and *Dermacentor reticulatus*. If ticks of some species (*Ixodes ricinus*, *Rhipicephalus sanguineus*) are present when the veterinary medicinal product is applied, all the ticks may not be killed within the first 48 hours.

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:

Bathing/immersion in water within two days after application of the veterinary medicinal product should be avoided. After weekly immersions in water for one minute the period of persistent insecticidal efficacy against fleas was 7 weeks.

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 and cats 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:

Avoid contact with the animal's eyes. In the 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 the 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 off immediately with soap and water.

Wash hands after use.

People with known hypersensitivity to fipronil or dimethyl sulfoxide or other 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.

Keep pipettes in original packaging and dispose of used pipettes immediately.

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.

Pregnancy and lactation:

Laboratory studies have not produced any evidence of teratogenic or embryotoxic effect. 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 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated once at five times the recommended dose. The risk of experiencing adverse effects (see section "Adverse

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

## 7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site alopecia (hair loss) <sup>1</sup> , Application site pruritus (itching) <sup>1</sup> , Application site erythema (reddening) <sup>1</sup> , Application site skin discolouration <sup>1</sup> General itching, Alopecia general (general hair loss) Hypersalivation, Vomiting Neurological signs <sup>3</sup> , Hyperaesthesia <sup>3</sup> Respiratory signs Depression <sup>3</sup>
Undetermined frequency (cannot be estimated from the available data)	Hypersalivation <sup>2</sup>

<sup>1</sup>Transient.

<sup>2</sup>May be observed for a brief period in the case of licking the administration site.

<sup>3</sup>Reversible.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

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

Route of administration and dosage:

External use only.

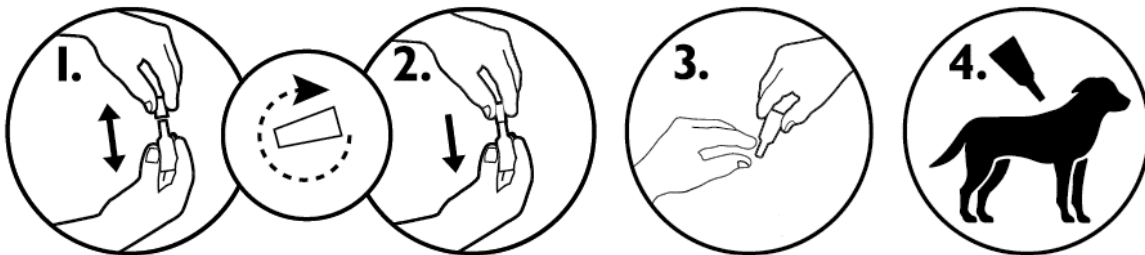
To ensure a correct dosage, body weight should be determined as accurately as possible.

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

Dogs	Number of pipettes	Pipette volume	Potency
over 2 kg and up to 10 kg	1 pipette	0.67 ml	67 mg
over 10 kg and up to 20 kg	1 pipette	1.34 ml	134 mg
over 20 kg and up to 40 kg	1 pipette	2.68 ml	268 mg
40 kg and up to 60 kg	1 pipette	4.02 ml	402 mg
over 60 kg	1 pipette + appropriate smaller pipette	4.02 ml + appropriate combination	402 mg + appropriate combination

Method of administration:

1. Remove the pipette from its packaging. Hold the pipette in an upright position, twist and pull the cap off.
2. Turn the cap around and place the other end of the cap back on the pipette. Push and twist the cap to break the seal, then remove the cap from the pipette.
3. Spread the animal hairs in the area between the shoulder blades to make the skin visible.
4. Put the tip of the pipette onto the skin and press the unit-dose pipette several times to empty its contents directly onto the skin at one or two spots.



**9. Advice on correct administration**

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.

Temporary changes to the coat (clumped/greasy hair and/or deposits on the hair) may be noted at the application site.

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 in the original container in order to protect from light and moisture.

The product should be maintained at room temperature (above 14° C) for approximately one hour prior to administration.

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

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 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**

Vm 01656/4087

Vm 01656/4088

Vm 01656/4089

Vm 01656/4090

White polypropylene pipette closed with either a polyethylene or polyoxymethylene cap. Each pipette is packed in a polyethylene terephthalate/aluminium/low density polyethylene triplex bag.

Pack sizes:

Box containing 1, 3, 6, 10, 20 or 30 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](http://www.gov.uk).

### **16. Contact details**

Marketing authorisation holder:

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

Local representatives and contact details to report suspected adverse reactions:

KRKA UK Ltd, United Kingdom, Tel: 02071 646 156, Email: [info.uk@krka.biz](mailto:info.uk@krka.biz)

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

**17. Other information**

NFA-VPS

*Gavin Hall*  
Approved: 19 February 2026