PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amflee 134 mg spot-on solution for medium dogs
Fipronil

2. STATEMENT OF ACTIVE SUBSTANCES

1 pipette (1.34 ml) contains:

Active substance:
Fipronil 134 mg

Excipients:
Butylhydroxyanisole (E320) 0.27 mg
Butylhydroxytoluene (E321) 0.13 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 unit-dose pipettes of 1.34 ml
3 unit-dose pipettes of 1.34 ml
6 unit-dose pipettes of 1.34 ml
10 unit-dose pipettes of 1.34 ml
20 unit-dose pipettes of 1.34 ml
30 unit-dose pipettes of 1.34 ml

5. TARGET SPECIES

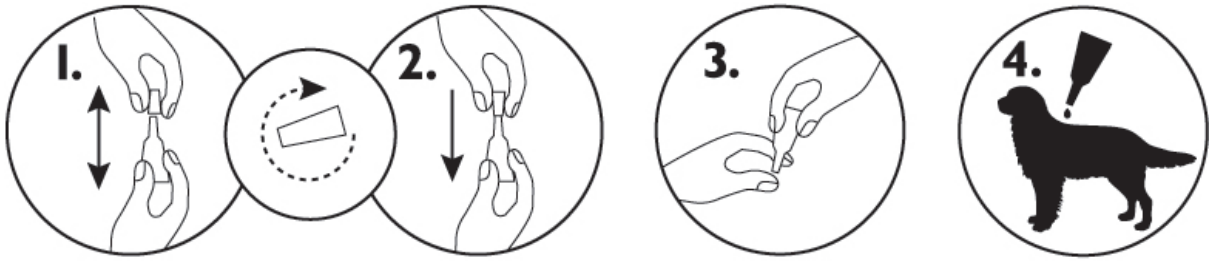
Dogs (10-20 kg)

6. INDICATION(S)

Treatment of fleas, ticks and lice.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For external use only.
Administer 1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight by topical application to the skin according to the bodyweight as follows:



8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

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.

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

Disposal: read package leaflet. Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 01656/4088

17. MANUFACTURER’S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amflee 134 mg spot-on solution for medium dogs
Fipronil

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil 134 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 unit-dose pipette of 1.34 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.
Dogs (10-20 kg)

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amflee 134 mg
Fipronil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

PACKAGE LEAFLET FOR:

Amflee 67/134/268/402 mg spot-on solution for 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:
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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amflee 67/134/268/402 mg spot-on solution for dogs
Fipronil

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

Each unit dose (pipette) contains:

Unit dose	**Active substance**	**Strength**	**Excipient** Butylhydroxyanisole (E320)	**Excipient** Butylhydroxytoluene (E321)
Amflee 67 mg	Fipronil	67 mg	0.134 mg	0.067 mg
Amflee 134 mg	Fipronil	134 mg	0.27 mg	0.13 mg
Amflee 268 mg	Fipronil	268 mg	0.54 mg	0.27 mg
Amflee 402 mg	Fipronil	402 mg	0.80 mg	0.40 mg

Light yellow to yellow, clear liquid.

4. INDICATION(S)

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 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 product is applied, all the ticks may not be killed within the first 48 hours.
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 2 kg 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, dimethyl sulfoxide or to any of other excipients.

6. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation may be observed.
Among the very rare suspected adverse reactions, transient cutaneous reactions on the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. In very rare cases, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms), vomiting or respiratory symptoms have been observed 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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

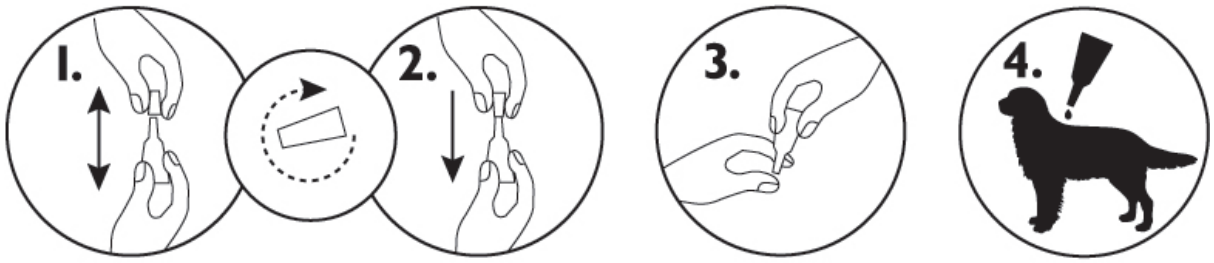
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Route of administration and dosage:
External use only.
Administer by topical application to the skin according to the bodyweight as follows:

Dogs	Number of pipettes	Pippete 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 the triplex bag. 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 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.
The hair should be parted and the product applied to the skin. 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 PERIOD

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. 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.
Do not use this veterinary medicinal product after the expiry date which is stated on packaging after {EXP}.

12. SPECIAL WARNING(S)

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

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 are recommended, and other dogs and cats in the household should be treated with a suitable insecticide.

For optimal control of flea infestation in multi-pet household, all animals in the household (e. g. dogs, cats, ferrets, rabbits) 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 and thoroughly flush the eyes with 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.

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

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 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.
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 a 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 the original packaging and dispose of used pipettes immediately.

Pregnancy and lactation:
Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effect. The safety of the product has not been established in breeding, pregnant and lactating bitches. Use only according to the benefit/risk assessment by the responsible veterinarian.

Overdose (symptoms, emergency procedures, antidotes):
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 6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

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

15. OTHER INFORMATION

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.
Box containing 1, 3, 6, 10, 20 or 30 pipettes.

Not all pack sizes may be marketed.

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

Approved 03 March 2020