

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amflee 402 mg spot-on solution for extra large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.02 ml pipette contains:

Active substances:

Fipronil 402 mg

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylhydroxyanisol (E320)	0.80 mg
Butylhydroxytoluene (E321)	0.40 mg
Polysorbate 80	
Povidone K25	
Dimethyl sulfoxide	to 4.02 ml

Light yellow to yellow, clear liquid.

3. CLINICAL INFORMATION

3.1 Target species

Dogs (> 40 kg)

3.2 Indications for use for each target species

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.

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

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.

3.5 Special precautions for use

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.

3.6 Adverse events

Dogs:

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

¹Transient.

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

³Reversible.

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:

Laboratory studies have not produced any evidence of teratogenic or embryotoxic effects. 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:

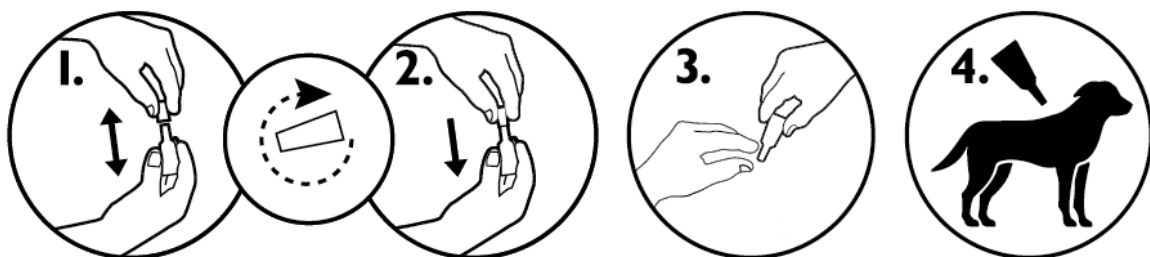
External use only.

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 up to 60 kg bodyweight, and one pipette of 4.02 ml and an appropriate smaller pipette per dog weighing over 60 kg bodyweight.

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

Method of administration:

Remove the pipette from its 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. Push and twist the cap to break the seal, then remove the cap from the pipette. Spread the animal hairs in the area between the shoulder blades to make the skin visible. 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.



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

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

Not applicable.

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*,) and lice (*Trichodectes canis*) in the dog. Ticks will usually be killed within 48 h after contact with Fipronil, however if ticks of some species (*Ixodes ricinus*, *Rhipicephalus sanguineus*) are already present when the veterinary medicinal product is applied, all of the ticks may not be killed within the first 48 hours. Fleas will be killed within 24 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: 3 years.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

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.

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.

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 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

KRKA, d.d., Novo mesto

7. MARKETING AUTHORISATION NUMBER

Vm 01656/4090

8. DATE OF FIRST AUTHORISATION

27 May 2015

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

December 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 19 February 2026