

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE  
{BOX}**

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

AMFLEE combo 50 mg/60 mg spot-on solution for cats and ferrets

Fipronil/S-Methoprene

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 0.5 ml pipette contains:

**Active substances:**

Fipronil	50 mg
S-Methoprene	60 mg

**3. PHARMACEUTICAL FORM**

Spot-on solution.

**4. PACKAGE SIZE**

1 x 0.5 ml  
3 x 0.5 ml  
6 x 0.5 ml  
10 x 0.5 ml  
30 x 0.5 ml

**5. TARGET SPECIES**

CATS AND FERRETS.

**6. INDICATION(S)**

In cats: To be used against infestations with fleas, alone or in association with ticks and/or biting lice.

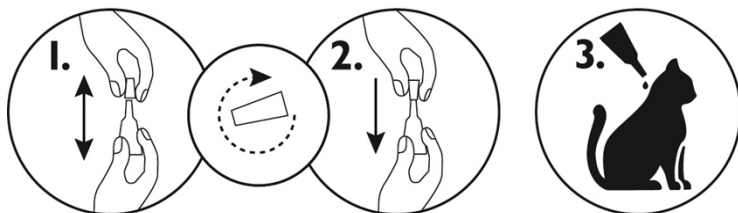
In ferrets: To be used against infestations with fleas, alone or in association with ticks.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

External use only.

Spot-on use.



**8. WITHDRAWAL PERIOD(S)**

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP:

**11. SPECIAL STORAGE CONDITIONS**

Store in the original package in order to protect from light and moisture.

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

Disposal: read package leaflet.

Fipronil and S-methoprene 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.

\*\*\*Only for those countries where the product is available on prescription:\*\*\*

To be supplied only on veterinary prescription.

**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(S)**

Vm 01656/4113

**17. MANUFACTURER'S BATCH NUMBER**

Lot

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

{BAG}

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

AMFLEE combo 50 mg/60 mg spot-on solution for cats and ferrets

Fipronil/S-Methoprene

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Each 0.5 ml pipette contains:

**Active substances:**

Fipronil	50 mg
S-Methoprene	60 mg

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

1 x 0.5 ml

**4. ROUTE(S) OF ADMINISTRATION**

Spot-on use.  
CATS AND FERRETS



**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 BLISTERS OR STRIPS**

{PIPETTE}

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

AMFLEE combo 50 mg/60 mg

Fipronil/S-Methoprene

**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:**  
**AMFLEE combo 50 mg/60 mg spot-on solution for cats and ferrets**

**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 combo 50 mg/60 mg spot-on solution for cats and

Fipronil/S-Methoprene

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

Each 0.5 ml pipette contains:

**Active substances:**

Fipronil	50 mg
S-Methoprene	60 mg

**Excipients:**

Butylhydroxyanisole (E320)	0.1 mg
Butylhydroxytoluene (E321)	0.05 mg

Clear yellow solution.

**4. INDICATION(S)**

In cats:

To be used against infestations with fleas, alone or in association with ticks and/or biting lice:

- Treatment of flea infestations (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for six weeks after application.
- Treatment of tick infestations (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 2 weeks against ticks.

- Treatment of infestations with biting lice (*Felicola subrostratus*).

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.

In ferrets:

To be used against infestations with fleas, alone or in association with ticks:

- Treatment of flea infestations (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas.
- Treatment of tick infestations (*Ixodes ricinus*). The product has a persistent acaricidal efficacy for 4 weeks against ticks.

## 5. CONTRAINDICATIONS

In the absence of available data, the product should not be used on kittens less than 8 weeks old and/or weighing less than 1 kg. The product should not be used on ferrets less than 6 months old.

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

**Do not use in rabbits due to a risk of adverse reactions or even death.**

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

## 6. ADVERSE REACTIONS

Among the very rare suspected adverse reactions, transient skin reactions on the application site (scaling, local hair loss, itching, redness) and general itching or hair loss have been reported after use. Excessive salivation, reversible nervous signs (increased sensitivity to stimulation, depression, other nervous signs) or vomiting have also been observed after use.

In the case of licking the administration site, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

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.

Alternatively you can report via your national reporting system (national system details).



## 7. TARGET SPECIES

Cats and ferrets.

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

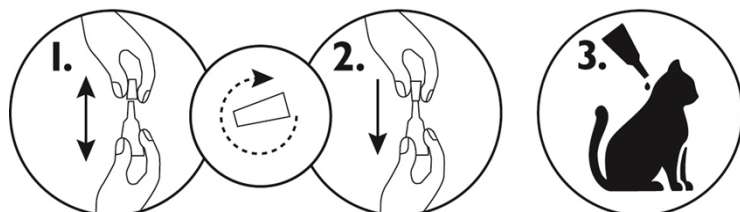
External use only, spot-on use.

One pipette of 0.5 ml per cat, corresponding to a minimum recommended dose of 5 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, by topical application to the skin.

One pipette of 0.5 mL per ferret corresponding to a dose of 50 mg for fipronil and 60 mg for (S)-methoprene per ferret, by topical application to the skin.

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. Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the pipette onto the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.



## 9. ADVICE ON CORRECT ADMINISTRATION

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 package in order to protect from light and moisture.

This veterinary medicinal product does not require any special temperature storage conditions

Do not use this veterinary medicinal product after the expiry date which is stated on the label after {EXP}. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNING(S)

### Special warnings for each target species:

All stages of fleas can infest the cat's basket, bedding, and regular resting areas such as carpets and soft furnishings. In cases of massive flea infestation and at the beginning of the control measures these areas should be treated with a suitable environmental insecticide product and vacuumed regularly. To reduce environmental flea challenge, all animals living in the same household should also be treated with a suitable flea control product.

For the treatment and control of flea allergy dermatitis it is recommended that allergic patients and all other animals in the household should be treated on a regular basis. No data on the effect of bathing/shampooing on the efficacy of the product in cats and ferrets are available. However, based on information available for dogs shampooed as from 2 days after application of the product, it is not recommended to bath animals within 2 days after application of the product.

### Special precautions for use in animals:

The attachment of single ticks after treatment cannot be ruled out. Therefore the transmission of infectious disease cannot be completely excluded if conditions are unfavourable.

For external use only. Do not administer orally.

Avoid contact with the eyes of the animal. If the product is in contact with eyes, rinse immediately with plenty of water.

Do not apply the product on wounds or skin lesions.

It is important to make sure that the veterinary medicinal product is applied directly onto an area of dry skin where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

Wait for the application site to dry before allowing the treated animal to come into contact with valuable fabrics or furnishings.

### Pregnancy and lactation:

#### In cats:

Laboratory studies in cats have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

The product can be used during pregnancy. The potential toxicity of the product for kittens of less than 8 weeks of age in contact with a treated queen is not documented. Special care should be taken in this case.

#### In ferrets:

The safety of the veterinary medicinal product has not been established in ferrets during pregnancy and lactation. Use only according to the risk-benefit assessment by the responsible veterinarian.

### Overdose (symptoms, emergency procedures, antidotes):

In cats overdose application of the product will cause a sticky appearance to the hairs at the application site. However, should this occur, it will disappear within 24 hours post application.

In ferrets aged 6 months and older and treated once every 2 weeks for four treatments, at five times the recommended dose, body weight loss was observed in some animals. The risk of experiencing adverse effects may increase with overdosing (see section 6 Adverse reactions).

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

This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided.

People with known hypersensitivity to fipronil or s-methoprene and/or any of the ingredients should avoid contact with the veterinary medicinal product.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

After accidental ocular exposure the eye should be rinsed carefully in clean water. Wash hands after use.

In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Do not smoke, drink or eat during application.

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 are not allowed to sleep with owners, especially children.

Keep pipettes in the original packaging until ready to use, and dispose of used pipettes immediately.

**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. The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

March 2021

**15. OTHER INFORMATION**

Cardboard box containing 1, 3, 6, 10, 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: 22/04/21

