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

5. TARGET SPECIES

CATS AND FERRETS.

6. INDICATION(S)

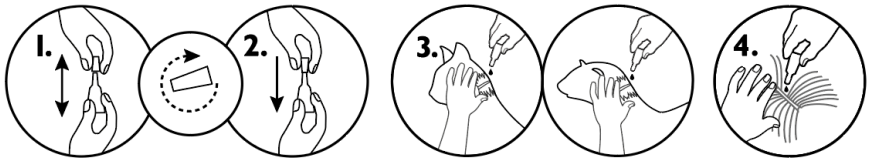
In cats: it kills fleas (*Ctenocephalides spp.*) for up to 4 weeks and prevents eggs laid by exposed fleas from developing for up to 6 weeks; it kills ticks (*Ixodes ricinus, Dermacentor variabilis, Rhipicephalus sanguineus*) for up to 2 weeks; it treats infestations with biting lice (*Felicola subrostratus*).

In ferrets: it kills fleas (*Ctenocephalides spp.*) for up to 4 weeks and prevents eggs laid by exposed fleas from developing for up to 6 weeks; it kills ticks (*Ixodes ricinus*) for up to 4 weeks.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

For external use only, topical spot-on application to the skin. One pipette of 0.5 ml per cat or ferret.



In the absence of safety studies, the minimum treatment interval is 4 weeks.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

For external use only.

Use during pregnancy and lactation

In cats
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 (female) 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.

Precautions

Single ticks may be attached after treatment and the transmission of infectious disease cannot be completely excluded in unfavourable conditions.
For external use only. Do not administer orally.
Avoid contact with the eyes of the animal. In such case, rinse the eyes immediately with plenty of water.
Do not apply the product on wounds or skin lesions.
Apply the product directly onto an area of dry skin where the animal cannot lick it off and prevent licking among animals following treatment.
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 from 2 days after application of the product, it is not recommended to bath animals within 2 days after application of the product.
Animals should be weighed accurately prior to treatment

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 (allergy) to Fipronil and (S)-methoprene) or to any other ingredients.
In the absence of studies, the use of the product is not recommended in non-target species.

User Warnings
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 (allergy) to fipronil, (s)-methoprene, polysorbates, alcohol, or additives E320 or E321, 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 eye contact, rinse carefully in clean water.
Wash hands after use.
If the product is accidentally swallowed, 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

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

Fipronil and s-methoprene may adversely affect aquatic organisms. Dispose of empty packaging and any remaining product in the household refuse.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
AVM-GSL

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 01656/5039

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:

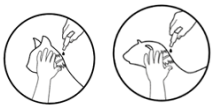
Fipronil	50 mg
S-Methoprene	60 mg

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”

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*).

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 (allergy) to Fipronil or (S)-methoprene or to any other ingredients. In the absence of safety studies, the minimum treatment interval is 4 weeks. In the absence of studies, the use of the product is not recommended in non-target species.

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.

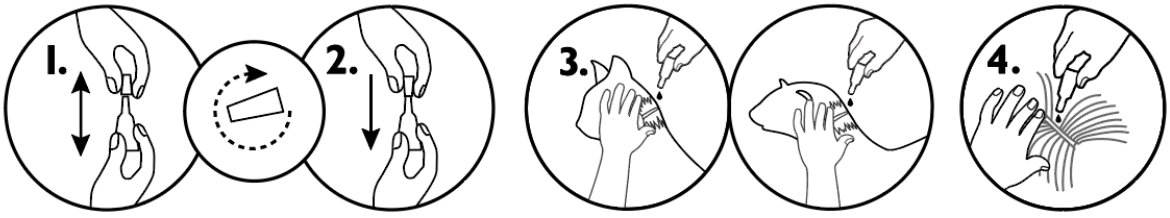
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

External use only, topical spot-on application to the skin.

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. Animals should be weighed accurately prior to treatment.

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. When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time.
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.

User warnings:
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 (allergy) to fipronil, (s)-methoprene, polysorbates, alcohol, or additives E320 or E321, 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 eye contact, rinse carefully in clean water.
Wash hands after use.
If the product is accidentally swallowed, 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.

Other precautions

The alcohol carrier may have adverse effects on painted, varnished or other household surfaces 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).

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Fipronil and s-methoprene may adversely affect aquatic organisms. Dispose of empty packaging and any remaining product in the household refuse.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

15. OTHER INFORMATION

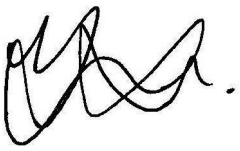
Cardboard box containing 1, 3, 6 pipettes.
Not all pack sizes may be marketed.

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

For animal treatment only

AVM-GSL

Vm 01656/5039



Approved: 30 September 2022