

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AMFLEE combo 50 mg/60 mg spot-on solution for cats and ferrets (AT, BE, CZ, EE, EL, ES, IT, NL, PL, PT, RO, UK)

FYPERIX combo 50 mg/60 mg spot-on solution for cats and ferrets (DE, FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml pipette contains:

Active substances:

Fipronil	50 mg
S-Methoprene	60 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylhydroxyanisole (E320)	0.1 mg
Butylhydroxytoluene (E321)	0.05 mg
Povidone (K25)	
Polysorbate 80	
Ethanol 96 per cent	
Diethylene glycol monoethyl ether	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats, ferrets.

3.2 Indications for use for each target species

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 veterinary medicinal product has a persistent acaricidal efficacy for up to 2 weeks against ticks.
- Treatment of infestations with biting lice (*Felicola subrostratus*).

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.

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 veterinary medicinal product has a persistent acaricidal efficacy for 4 weeks against ticks.

3.3 Contraindications

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

Do not use in sick animals (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 substances or to any of the excipients.

3.4 Special warnings

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 veterinary medicinal 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 veterinary medicinal product in cats and ferrets are available. However, based on information available for dogs shampooed as from 2 days after application of the veterinary medicinal product, it is not recommended to bath animals within 2 days after application of the veterinary medicinal product.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal product is in contact with eyes, rinse immediately with plenty of water.

Do not apply the veterinary medicinal 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.

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

This veterinary medicinal product can cause mucous membrane, skin and eye irritation. Therefore, contact of the veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cat, ferret¹:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site scaling ² , Application site hair loss ² , Application site itching ² , Application site reddening ² Itching General hair loss Hypersalivation ³ , Vomiting Neurological signs ⁴ , Hyperaesthesia ⁴ Depression ⁴
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¹ Undetermined frequency (cannot be estimated from the available data) for ferret

² Transient

³ May be observed briefly in the case of licking the administration site, also (mainly due to the nature of the carrier)

⁴ Reversible

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

Pregnancy:

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

Can be used during pregnancy.

Ferrets: the safety of the veterinary medicinal product has not been established during pregnancy. Use only according to the benefit-risk assessment by the responsible veterinarian.

Lactation:

Cats: the potential toxicity of the veterinary medicinal 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.

Ferrets: the safety of the veterinary medicinal product has not been established during lactation.
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

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.

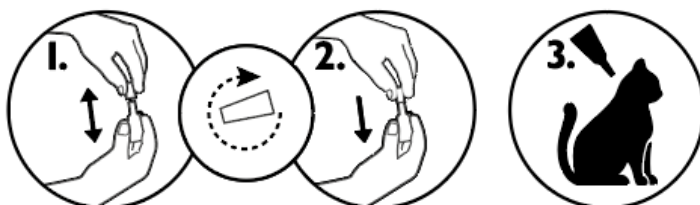
In the absence of safety studies, the minimum treatment interval is 4 weeks.

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.

The minimum treatment interval is 4 weeks.

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.



3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The risk of experiencing adverse events may increase with overdosing (see section 3.6).

In cats

No undesirable effects were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months.

Itching may occur following treatment.

Overdose application of the veterinary medicinal product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

In ferrets

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.

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: QP53AX65

4.2 Pharmacodynamics

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by interacting with ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), 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 acarines. Fipronil kills fleas within 24 hours, ticks (*Dermacentor variabilis*, *Rhipicephalus sanguineus*, *Ixodes scapularis*, *Ixodes ricinus*, *Haemaphysalis longicornis*, *Haemaphysalis flava*, *Haemaphysalis campanulata*) and lice within 48 hours post-exposure.

(S)-Methoprene is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues that inhibit the development of immature stages of insects. This compound mimics the action of juvenile hormone and causes impaired development and death of the developing stages of fleas. The on-animal ovicidal activity of (S)-methoprene results from either direct penetration of the eggshell of newly laid eggs or from absorption through the cuticle of the adult fleas. (S)-methoprene is also effective in preventing flea larvae and pupae from developing, which prevents contamination of the environment of treated animals with the immature stages of fleas.

4.3 Pharmacokinetics

Studies of metabolism of fipronil have demonstrated that the major metabolite is the sulfone derivative of fipronil.

(S)-methoprene is extensively degraded into carbon dioxide and acetate that are subsequently incorporated into endogenous materials.

The pharmacokinetic profiles after topical application of fipronil and (S)-methoprene in combination were studied in cats in comparison to intravenous dosing of fipronil or (S)-methoprene alone. This established absorption and other pharmacokinetic parameters under conditions mimicking clinical practice. The topical application, with additional potential oral exposure from licking, resulted in overall systemic absorption of fipronil (18%) with a mean maximum concentration (C_{max}) of approximately 100 ng/ml fipronil and 13 ng/ml of fipronil sulfone in plasma.

Peak fipronil plasma concentrations are rapidly attained (mean t_{max} approximately 6 h) and decline with a mean terminal half-life of approximately 25 h.

Fipronil is slightly metabolised to fipronil sulfone in cats.

Plasma concentrations of (S)-methoprene were generally below the limit of quantitation (20 ng/ml) in cats after topical application.

Both (S)-methoprene and fipronil, together with its major metabolite, are well-distributed in the haircoat of cats within one day after application. The concentrations of fipronil, fipronil sulfone and

(S)-methoprene in the hair coat decrease with time and are detectable for at least 59 days after dosing. Parasites are killed through contact rather than by systemic exposure. No pharmacological interaction between fipronil and (S)-methoprene was noted.

The pharmacokinetic profile of the veterinary medicinal product has not been investigated in ferrets.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

White polypropylene unit-dose pipette with polyethylene or polyoxymethylene closure with spike packaged into laminated triplex bag composed of polyester, aluminium and polyethylene.

Pack sizes:

Cardboard box containing 1, 3, 6, 10, 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 or household waste.

The veterinary medicinal product should not enter water courses as Fipronil and (S) methoprene may be dangerous for fish and other aquatic organisms.

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

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription (AT, BE, GR).

Veterinary medicinal product not subject to prescription (CZ, DE, EE, FR, IT, NL, PL, PT, RO, SK, ES).

Veterinary medicinal product subject to prescription except for some pack sizes (CZ).

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AMFLEE combo 50 mg/60 mg spot-on solution (AT, BE, CZ, EE, EL, ES, IT, NL, PL, PT, RO, UK)
FYPERIX combo 50 mg/60 mg spot-on solution (DE, FR)

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.5 ml pipette contains:

fipronil	50 mg
s-methoprene	60 mg

3. 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

4. TARGET SPECIES

Cats, Ferrets



5. INDICATIONS

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.

For products not subject to veterinary prescription:



Ixodida



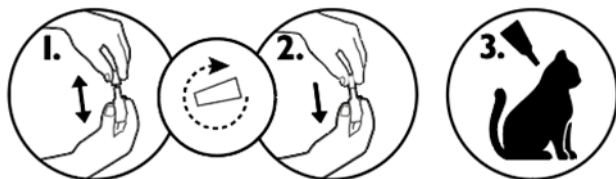
Ctenocephalides felis



Felicola subrostratus

6. ROUTES OF ADMINISTRATION

External use only.
Spot-on use.



7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.

9. SPECIAL STORAGE PRECAUTIONS

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

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

Marketing authorisation holder:
To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**BAG****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AMFLEE combo spot-on solution for cats and ferrets (AT, BE, CZ, EE, EL, ES, IT, NL, PL, PT, RO, UK)

FYPERIX combo spot-on solution for cats and ferrets (DE, FR)

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

fipronil /s-methoprene

50 mg/60 mg

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.

Marketing authorisation holder

To be completed nationally.

5. 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 combo (AT, BE, CZ, EE, EL, ES, IT, NL, PL, PT, RO, UK)

FYPERIX combo (DE, FR)

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

50 mg/60 mg

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AMFLEE combo 50 mg/60 mg spot-on solution for cats and ferrets (AT, BE, CZ, EE, EL, ES, IT, NL, PL, PT, RO, UK)

FYPERIX combo 50 mg/60 mg spot-on solution for cats and ferrets (DE, FR)

2. Composition

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.

3. Target species

Cats and ferrets.



4. Indications for use

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 veterinary medicinal product has a persistent acaricidal efficacy for up to 2 weeks against ticks.
- Treatment of infestations with biting lice (*Felicola subrostratus*).

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.

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 veterinary medicinal product has a persistent acaricidal efficacy for 4 weeks against ticks.

5. Contraindications

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

Do not use in sick animals (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 substances or to any of the excipients.

6. Special warnings

Special warnings:

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 veterinary medicinal 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 veterinary medicinal product in cats and ferrets are available. However, based on information available for dogs shampooed as from 2 days after application of the veterinary medicinal product, it is not recommended to bath animals within 2 days after application of the veterinary medicinal product.

Special precautions for safe use in the target species:

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 veterinary medicinal product is in contact with eyes, rinse immediately with plenty of water.

Do not apply the veterinary medicinal 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.

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

This veterinary medicinal product can cause mucous membrane, skin and eye irritation. Therefore, contact of the veterinary medicinal 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.

Pregnancy:

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

Can be used during pregnancy.

Ferrets: the safety of the veterinary medicinal product has not been established during pregnancy.

Use only according to the benefit-risk assessment by the responsible veterinarian.

Lactation:

Cats: the potential toxicity of the veterinary medicinal 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.

Ferrets: the safety of the veterinary medicinal product has not been established during lactation.

Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose:

The risk of experiencing adverse events may increase with overdosing (see section “Adverse events”).

In cats: no undesirable effects were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months. Itching may occur following treatment. Overdose application of the veterinary medicinal product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

In ferrets: in animals 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.

7. Adverse events

Cat, ferret¹:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site scaling ² , Application site hair loss ² , Application site itching ² , Application site reddening ² Itching General hair loss Hypersalivation ³ , Vomiting Neurological signs ⁴ , Hyperaesthesia ⁴ Depression ⁴
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¹ Undetermined frequency (cannot be estimated from the available data) for ferret

² Transient

³ May be observed briefly in the case of licking the administration site, also (mainly due to the nature of the carrier)

⁴ Reversible

Reporting adverse events is important. It allows continuous safety monitoring of a 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: {national system details}.

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

External use only, spot-on use.

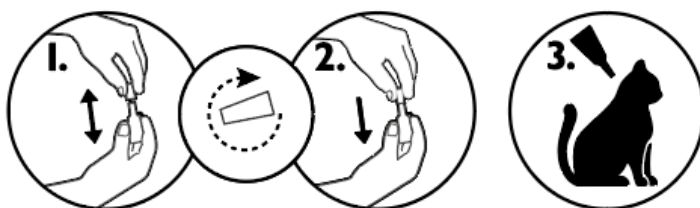
One pipette of 0.5 ml per cat, corresponding to a minimum recommended dose of 5 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, by topical application to the skin.

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

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:

4. Remove the pipette from its packaging. Hold the pipette in an upright position, twist and pull the cap off.
5. 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.
6. 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 periods

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 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 or household waste.

The veterinary medicinal product should not enter water courses as Fipronil and (S) methoprene may be dangerous for fish and other aquatic organisms.

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 subject to prescription (AT, BE, GR).

Veterinary medicinal product not subject to prescription (CZ, DE, EE, FR, IT, NL, PL, PT, RO, SK, ES).

Veterinary medicinal product subject to prescription except for some pack sizes (CZ).

14. Marketing authorisation numbers and pack sizes

White polypropylene unit-dose pipette with polyethylene or polyoxymethylene closure with spike packaged into laminated triplex bag composed of polyester, aluminium and polyethylene.

Pack sizes:

Cardboard box containing 1, 3, 6, 10, 30 pipettes.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

To be completed nationally.

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:

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