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

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FYPERIX combo 50 mg/60 mg spot-on solution for cats and ferrets
Fipronil/S-Methoprene

## 2. STATEMENT OF ACTIVE AND OTHER 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

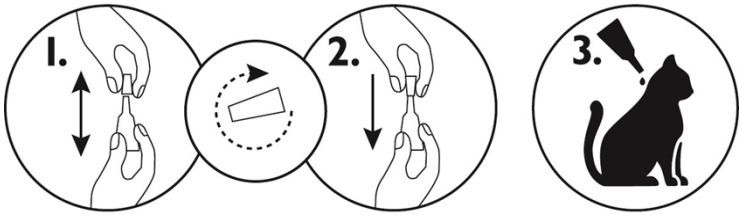
CATS AND FERRETS.

## 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

## 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

Vm 01656/4108

## 17. MANUFACTURER'S BATCH NUMBER

Lot

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

**{BAG}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FYPERIX 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

FYPERIX 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 FOR:

FYPERIX 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 and manufacturer responsible for batch release :
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

- Elimination of fleas (*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.
- Elimination of ticks (*Ixodes ricinus, Dermacentor variabilis, Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 2 weeks against ticks.
- Elimination of 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:

- Elimination of fleas (*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.

Elimination of ticks (*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

Do not overdose.

In cats
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.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Cats and ferrets.

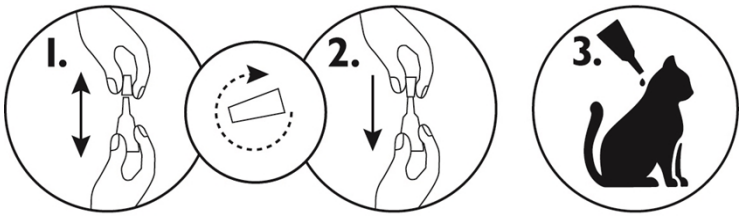
## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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)

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.
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.
Avoid the contact with the animal’s eyes.

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.
There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.
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 is not documented. Special care should be taken in this case.
In ferrets: Laboratory studies in cats have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. 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.
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 a known hypersensitivity to insecticides or alcohol should avoid contact with the 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.

## 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 and S-methoprene 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

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: 04/05/2016**