PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fyperix 50 mg spot-on solution for cats
Fyperix vet 50 mg spot-on solution for cats
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 pipette (0.50 ml) contains:

Active substance:
Fipronil 50 mg

Other ingredients:
Butylhydroxyanisole (E320) 0.10 mg
Butylhydroxytoluene (E321) 0.05 mg

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 unit-dose pipettes of 0.5 ml
3 unit-dose pipettes of 0.5 ml
6 unit-dose pipettes of 0.5 ml
10 unit-dose pipettes of 0.5 ml
20 unit-dose pipettes of 0.5 ml
30 unit-dose pipettes of 0.5 ml

5. TARGET SPECIES

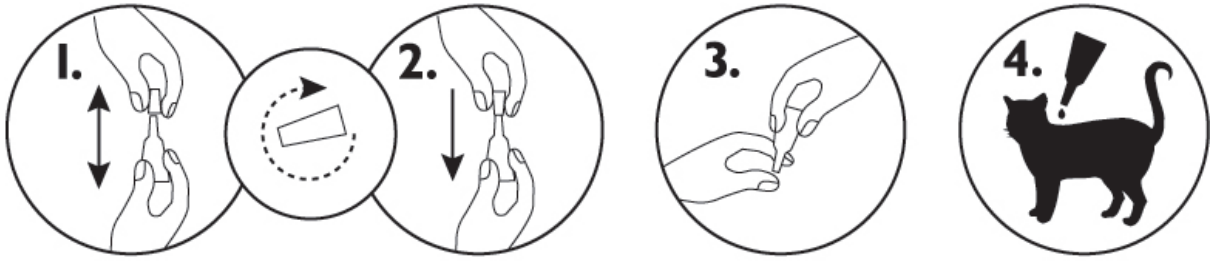
Cats

6. INDICATION(S)

Treatment of fleas and ticks.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Spot-on use.
Administer by topical application to the skin 1 pipette of 0.5 ml per animal.



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 container in order to protect from light and moisture.
The product should be maintained at room temperature (above 14°C) for approximately one hour prior to administration.

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

Disposal: read package leaflet.
Fipronil 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.

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 01656/4036

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fyperix 50 mg spot-on solution for cats
Fyperix vet 50 mg spot-on solution for cats
Fipronil

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil 50 mg

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

1 unit-dose pipette of 0.5 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.

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 SMALL IMMEDIATE PACKAGING UNITS

PIPETTE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fyperix 50 mg
Fyperix vet 50 mg
Fipronil

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

0.5 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PACKAGE LEAFLET FOR:

Fyperix 50 mg spot-on solution for cats
Fyperix vet 50 mg spot-on solution for cats

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 50 mg spot-on solution for cats
Fyperix vet 50 mg spot-on solution for cats
Fipronil

Fyperix 50 mg spot-on solution for cats (United Kingdom, France, Germany, Portugal, Spain, Netherlands, Italy)
Fyperix vet 50 mg spot-on solution for cats (Denmark, Finland, Sweden, Norway)

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

1 pipette (0.50 ml) contains:

Active substance:

Fipronil	50 mg

Other ingredients:

Butylhydroxyanisole (E320)	0.10 mg
Butylhydroxytoluene (E321)	0.05 mg

Light yellow to yellow, clear liquid.

4. INDICATION(S)

Treatment of fleas (*Ctenocephalides* spp.) and tick (*Ixodes ricinus*) infestations.

The product has a persistent insecticidal efficacy for up to 4 weeks against fleas (*Ctenocephalides* spp.) and acaricidal efficacy for up to 4 weeks against *Ixodes ricinus* and for up to 1 week against *Dermacentor reticulatus* and *Rhipicephalus sanguineus*. If ticks of some species (*Dermacentor reticulatus* and *Rhipicephalus*

sanguineus) are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

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.

5. CONTRAINDICATIONS

In the absence of available data, the product should not be used on kittens less than 2 months old and/or weighing less than 1 kg.
Do not use on sick (e.g. systemic diseases, fever…) or convalescent animals.
Do not use in rabbits, as adverse reactions and even death could occur.
Do not use in known cases of hypersensitivity to fipronil, dimethyl sulphoxide or to any of the excipients.

6. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation may be observed.
Among the extremely rare suspected adverse reactions, transient cutaneous reactions on the application site (squamosis, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms) or vomiting have been observed after use.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

7. TARGET SPECIES

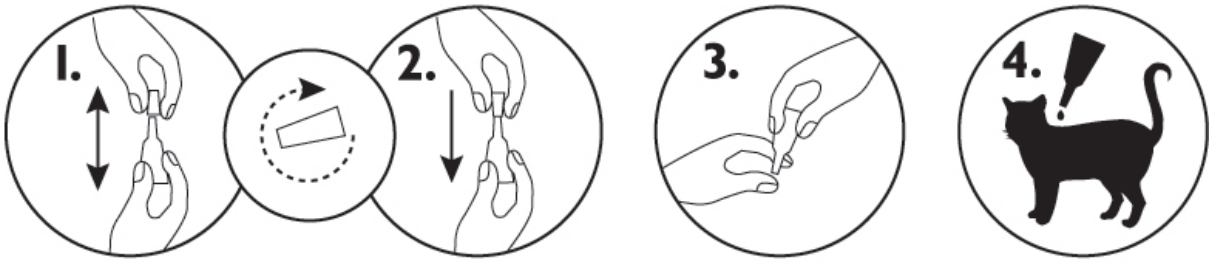
Cats

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

Route of administration and dosage:
External use only.
Administer by topical application to the skin 1 pipette of 0.5 ml per animal.
Method of administration:

1. Remove the pipette from the triplex bag. 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. Spread the hairs of the animal between the shoulder blades to make the skin visible.
4. Place the tip of the pipette on the skin and squeeze gently to empty its contents onto the skin, preferably at two spots, one at the base of the skull and a second 2-3 cms further back.



The hair should be parted and the product applied to the skin.
Temporary changes to the coat (clumped/greasy hair and/or deposits on the hair) may be noted at the application site which normally disappears within 24 hours.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original container in order to protect from light and moisture.
The product should be maintained at room temperature (above 14°C) for approximately one hour prior to administration.
Do not use this veterinary medicinal product after the expiry date which is stated on packaging after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

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.

The product does not prevent ticks from attaching to the animals. If the animal has been treated prior to exposure to the ticks, the tick 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.

No data on the effect of bathing/shampooing on the efficacy of the product in cats are available. However, based on information available for dogs, weekly immersion in water for one minute reduces the period of persistent insecticidal efficacy against fleas by one week.

For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.
When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended.
Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

Do not apply the product on wounds or damaged skin.

Animals should be weighed accurately prior to treatment.

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.

No adverse effects were observed in target animal safety studies in cats and kittens aged 2 months and older and weighing about 1 kg treated once a month at five times the recommended dose for three consecutive months. The risk of experiencing adverse effects may however increase with overdosing (see section 6).

Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this product in pregnant and lactating queens. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

User warnings:

This product can cause mucous membrane and eye irritation. Therefore, contact between the 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 and show the package leaflet or the label to the physician.
Avoid contents coming into contact with the fingers. If this occurs, wash off immediately with soap and water.
Wash hands after use.
Do not smoke, drink or eat during application.
People with a 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.

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 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

White polypropylene pipette closed with either a polyethylene or polyoxymethylene cap. Each 0.5 ml pipette is packed in a polyethylene terephthalate/aluminium/low density polyethylene triplex bag.
Box containing 1, 3, 6, 10, 20 or 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: 03 May 2017