

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Katkin DE:FLEA 50 mg/60 mg spot-on solution for cats
Fipronil/S-methoprene

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each pipette contains:

Active substances:

50 mg fipronil
60 mg S-methoprene

Excipients:

0.134 mg butylhydroxyanisole (E320)
0.067 mg butylhydroxytoluene (E321).

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

6. INDICATION(S)

Kills fleas (*Ctenocephalides spp.*) on treated cats for up to 4 weeks and prevents eggs laid by exposed fleas from developing for up to 6 weeks. Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*) on treated cats for up to 2 weeks. Treats infestations with biting lice (*Felicola subrostratus*).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

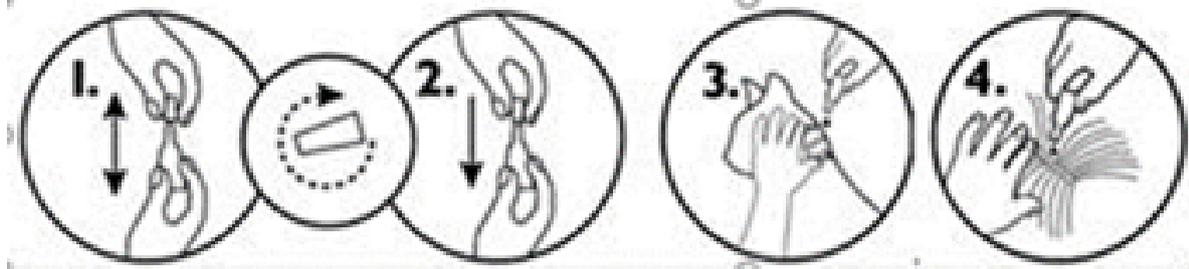
Spot-on solution.

For external use only, topical spot-on application to the skin. Do not administer orally.

Dose:

One pipette of 0.5 ml per cat.

How to apply:



1. Hold pipette upright. Twist and pull cap off.
2. Use the tip of cap to break seal.
3. Part the coat on the back of the animal until the skin is visible
4. Apply pipette to one spot of the skin and squeeze to empty.

Make sure you apply the product to a spot where your cat can't lick it off, and don't let other pets lick it off either. Always leave a minimum period of 4 weeks between treatments. Temporary changes to the coat (clumped/ greasy hair) may be noted at the application site.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Contraindications:

Only use on cats aged 8 weeks or older, weighing more than 1 kg. Do not use if your cat is sick or recovering from illness. Do not use in cats hypersensitive (allergic) to the active substances (fipronil or (S)-methoprene) or any other excipients (ingredients).

Do not use in rabbits due to a risk of adverse reactions, including death.

Do not apply on wounds or damaged skin.

User Safety

Please read before every use.

This product can cause mucous membrane, skin, and eye irritation.

Contact of the product with the mouth, skin and eyes should be avoided.

People with a known hypersensitivity (allergy) to fipronil, S-methoprene or other ingredients should avoid contact with this product.

If the product comes into contact with your fingers, wash hands with soap and water.

After accidental eye contact, rinse carefully in clean water. If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the doctor.

Wash hands after use. Do not smoke, drink, or eat during application.
Treated cats should not be handled until the application site is dry, and children should not be allowed to play with treated cats until the application site is dry. It is therefore recommended that cats 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 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

Vm 01656/3028

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Katkin DE:FLEA 50 mg/60 mg spot-on solution for cats
Fipronil/S-methoprene

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each pipette contains 50 mg fipronil, 60 mg S-methoprene

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

Pipette 1 x 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 BLISTERS OR STRIPS

{PIPETTE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Katkin DE:FLEA 50 mg/60 mg spot-on solution for cats
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:

Katkin DE:FLEA 50 mg/60 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

Katkin DE:FLEA 50 mg/60 mg spot-on solution for cats
Fipronil/S-methoprene

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

Each 0.5 ml pipette contains:

Active substances:

Fipronil	50 mg
S-methoprene	60 mg

Excipients:

Butylhydroxyanisole (E320)	0.134 mg
Butylhydroxytoluene (E321)	0.067 mg

Clear yellow solution.

4. INDICATION(S)

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

- Kills fleas (*Ctenocephalides* spp.) on treated cats for up to 4 weeks and prevents eggs laid by exposed fleas from developing for up to 6 weeks.
- Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*) on treated cats for up to 2 weeks.
- Treats infestations with biting lice (*Felicola subrostratus*).

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.

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

Do not use if your cat has a hypersensitivity (allergy) to the active substances (fipronil or (S)-methoprene) or to any of the excipients (ingredients).

Do not use in rabbits, as adverse drug reactions, including death, could occur.

Do not use in any other 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).

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 using the contact details at the end of this leaflet, or via your national reporting system <{national system details}>.

7. TARGET SPECIES

Cats

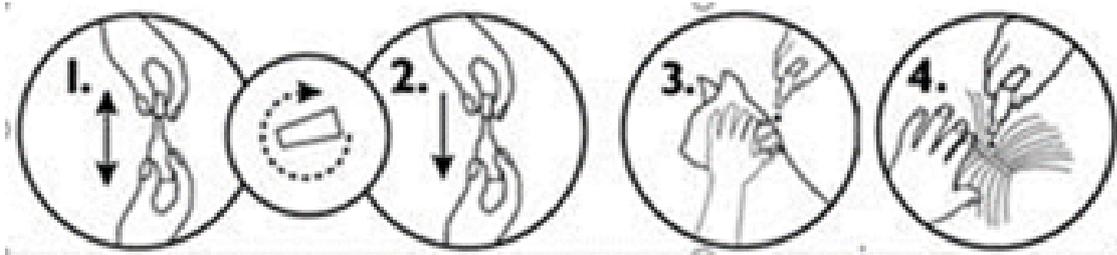
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

One pipette containing 0.5 ml should be used for each cat (corresponding to a minimum recommended dose of 5 mg/kg for fipronil and 6 mg/kg for (S)-methoprene), applied to the skin as directed below.

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. Apply to the skin at the base of the neck in front of the shoulder blades. Part the coat until the skin is visible.
4. 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.



Do not overdose. Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

9. ADVICE ON CORRECT ADMINISTRATION

In the absence of safety studies, the minimum treatment interval is 4 weeks. Animals should be weighed accurately prior to treatment.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light and moisture. 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:

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

Bathing and/or shampooing should be avoided. No information on the effect of bathing or the use of a shampoo on the effectiveness of the product in cats is available. Based on information available for dogs, bathing/immersion in water within 2 days after application of the product and more frequent bathing than once a week should be avoided.

Special precautions for use in animals:

For external use only. Do not administer orally. Avoid contact with the animal's eyes. If the product is in contact with eyes, rinse immediately with plenty of water.

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. Do not apply the product on wounds or skin lesions.

There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable. 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.

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 a known hypersensitivity (allergy) 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 with clean water. If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the physician.

Wash hands after use.

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

Pregnancy and lactation:

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.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with other flea products which are applied directly on to the animal.

Overdose (symptoms, emergency procedures, antidotes):

The risk of experiencing adverse effects may increase with overdosing (see section 6 Adverse reactions).

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

Other precautions

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

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

Dispose of waste material in accordance with local requirements.

Medicines should not be disposed of via wastewater.

Fipronil and s-methoprene 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

September 2023

15. OTHER INFORMATION

White polypropylene single-dose pipette packaged in aluminium foil sachets.

Cardboard box containing 1, 3 or 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:

AVM- GSL

For animal treatment only.Vm 01656/3028

Local representative:

KRKA UK Ltd, United Kingdom, Tel: 02071 646 156, Email: info.uk@krka.biz

Approved 01 September 2023

A handwritten signature in black ink, appearing to be 'M. M. M.', located below the approval date.