PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipmetho Combo 50 mg/60 mg spot-on solution for cats
Fipronil, S-methoprene

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

WHAT'S IN THIS PRODUCT?
Each pipette contains 50 mg fipronil, 60 mg S-methoparene (active ingredients), 0.1 mg Butylhydroxyanisole (E320) and 0.05 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)

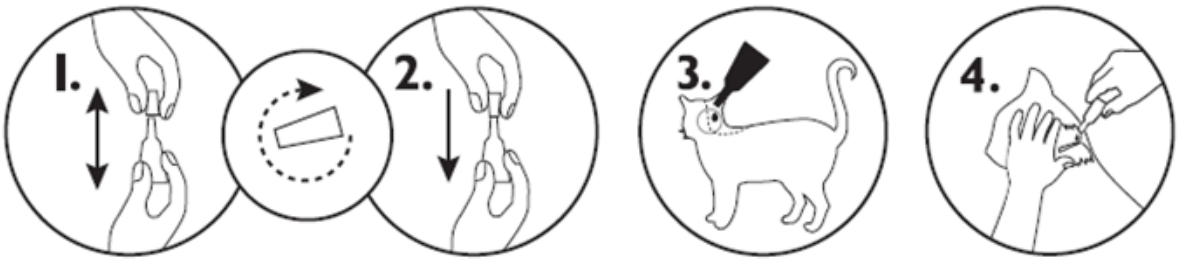
- Kills fleas, ticks and lice
- Protects for up to 4 weeks against fleas

WHAT DOES THIS PRODUCT DO?
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.

How to apply this product



1 x Treatment

HOW DO I USE THIS PRODUCT?
Before use, read the package leaflet for full instructions and all warnings, including user warnings. Hold the pipette in an upright position, tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette, twist and pull the cap off. 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. 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. Do not reapply more often than at four-weekly intervals.
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.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.
Read the package leaflet before use.

IS THIS PRODUCT SUITABLE FOR MY PET?
Only use Fipmetho Combo if your cat is aged 8 weeks or older, and weighs more than 1 kg. Do not use if your pet is sick or recovering from an illness. Do not use if your cat has a hypersensitivity to the active substances or to any of the excipients. Do not apply on wounds or damaged skin. Do not use on rabbits as adverse reactions, including death could occur.

USER SAFETY- Please read before every use.
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 in 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.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

HOW SHOULD I STORE THE PRODUCT
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.

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

HOW SHOULD I DISPOSE OF THE PRODUCT
Dispose of waste material 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.

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 01656/5027

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipmetho Combo 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

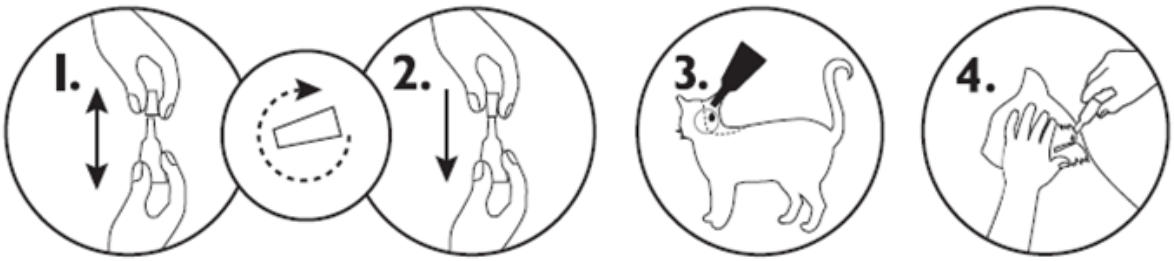
3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 x 0.5 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.
Cats

How to apply this product



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

Fipmetho 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 FOR:

Fipmetho **Combo 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

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipmetho Combo 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

4. INDICATION(S)

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*).

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 in cases of hypersensitivity to the active substances or to any of the excipients..
Do not use in rabbits, as adverse drug reactions with even mortality 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 1000 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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

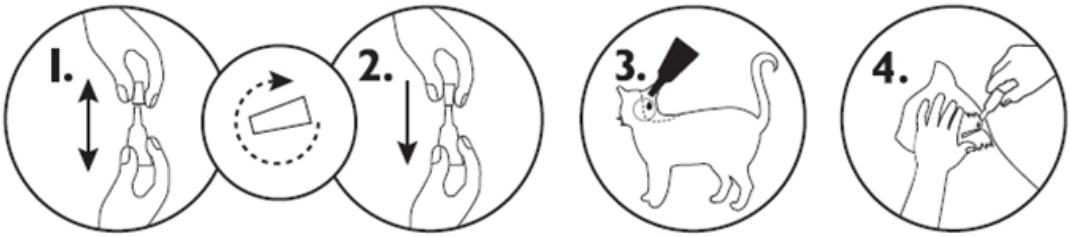
7. TARGET SPECIES

Cats.

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

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.

Method of administration:
1. Remove the pipette from its packaging. Hold the pipette in an upright position, tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette, 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

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

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

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.

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:
Animals should be weighed accurately prior to treatment.
Avoid 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.
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.

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

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 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):
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.
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

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

December 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk

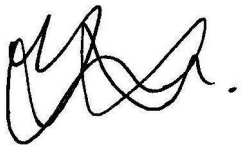
15. OTHER INFORMATION

Available in cartons containing 1, 3 or 6 pipettes.
Not all pack sizes may be marketed.

AVM-GSL

For animal treatment only.

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



Approved: 07 March 2024