

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Combo 50 mg/60 mg spot-on solution for cats (UK)
Fipronil, S-Methoprene

2. STATEMENT OF ACTIVE SUBSTANCES

WHAT'S IN THIS PRODUCT?

Each pipette contains 50 mg fipronil, 60 mg S-methoprene (active ingredients).

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)

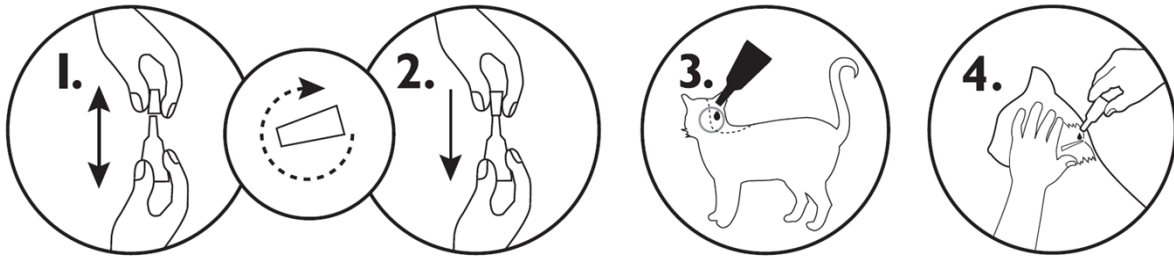
WHAT DOES THIS PRODUCT DO?

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, 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. Apply to the skin at the base of the neck in front of the shoulder blades.

Part the coat 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

Read the package leaflet before use.

IS THIS PRODUCT SUITABLE FOR MY PET?

Only use Fiprotec 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 pet has a hypersensitivity to fipronil or S-methoprene or the other ingredients. 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 fipronil, S-methoprene, insecticides or alcohol 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. 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

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

HOW SHOULD I STORE AND DISPOSE OF THE PRODUCT

Store below 30 °C.

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 STORE AND 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.

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(S)

Vm 01656/4122

17. MANUFACTURER’S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Combo 50 mg/60 mg spot-on solution for cats (UK)
Fipronil, S-Methoprene

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

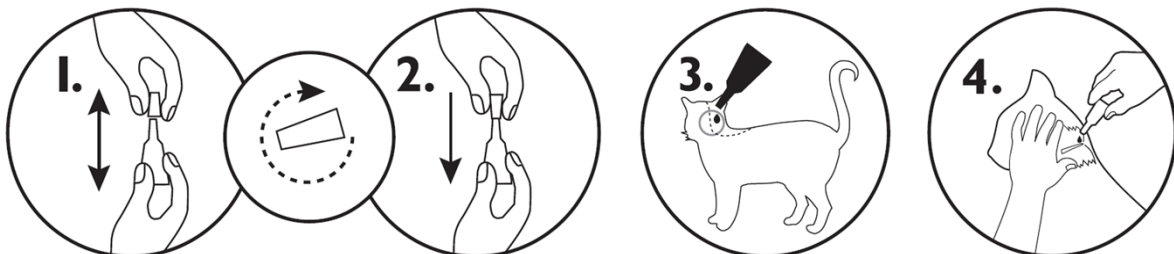
3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 x 0.5 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.

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

Fiprotec Combo 50 mg/60 mg (UK)
Fipronil, S-Methoprene

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Krka d.d., Novo mesto

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

National PIL UK

Fiprotec Combo 50 mg/60 mg spot-on solution for cats

READ THIS INFORMATION CAREFULLY BEFORE EACH USE. KEEP THIS LEAFLET IN THE OUTER CARTON FOR FUTURE REFERENCE.

What is Fiprotec Combo for?

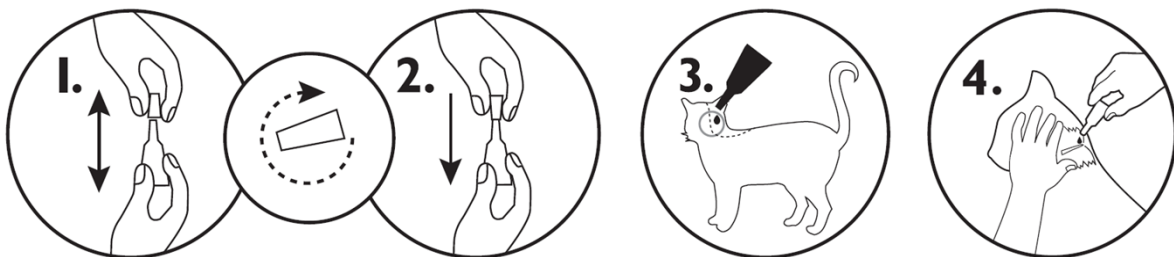
Fiprotec Combo spot-on solution for cats is used against infestations with fleas *Ctenocephalides* spp. (including their eggs and juvenile forms) and/or ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*) and/or biting lice (*Felicola subrostratus*).

Efficacy against fleas lasts for up to 4 weeks and against their multiplication for up to 6 weeks. Efficacy against ticks lasts for up to 2 weeks.

How do I use Fiprotec Combo?

Animals should be weighed accurately prior to treatment; do not use in kittens weighing less than 1 kg.

One tube should be given to each cat, applied to the skin as shown below.



Remove the pipette from its packaging. Hold the pipette in an upright position, 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.

Apply to the skin at the base of the neck in front of the shoulder blades.

Part the coat 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.

After treatment, you may notice transient clumping of hair or greasiness at the application site.

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.

If cats lick the product, it can cause them to salivate (drool) for a brief period of time.

In very rare cases, redness or discolouration of the skin, hair loss and itching may occur at the treatment site or on the cat in general. Excess salivation, reversible nervous signs (depression, hypersensitivity) or vomiting have been seen in exceptional cases.

Bathing and/or shampooing of treated cats is not recommended. No information on the effect of bathing or the use of a shampoo on the effectiveness of the product in cats is available.

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

What is in Fiprotec Combo?

	Contents			
	Active substance		Other ingredients	
Fiprotec Combo	Amount of fipronil	Amount of S-Methoprene	Butylhydroxyanisole (E320)	Butylhydroxytoluene (E321)
50 mg/60 mg spot-on solution for cats	50 mg	60 mg	0.1 mg	0.05 mg

How often should I use Fiprotec Combo?

Always leave a minimum period of 4 weeks between treatments. Adult fleas are killed for up to 4 weeks. Ticks are killed for up to 2 weeks. When a continued risk of flea and/or tick infestation is anticipated the treatment can be repeated every 4 weeks.

Should I use anything else with Fiprotec Combo?

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.

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

Animal safety with Fiprotec Combo

Do not use on kittens less than 8 weeks old or weighing less than 1 kg.

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

Do not use on sick or convalescent animals.

Do not use if your cat has a hypersensitivity to fipronil or S-methoprene or the other ingredients.

Do not apply on wounds or damaged skin.

Avoid contact with your cat's eyes. If this occurs, immediately and thoroughly flush with water. If necessary, speak to your veterinary surgeon for advice.

In cats, the product can be used during pregnancy. No specific studies have been performed in lactating cats. Consult your veterinary surgeon before using the product in lactating cats or animals in contact with kittens less than 8 weeks old.

Speak to your veterinary surgeon if you notice any adverse effects following the use of Fiprotec Combo, even those not already listed in the package leaflet or you think that the medicine has not worked.

User safety with Fiprotec Combo

PLEASE READ THESE WARNINGS BEFORE EACH USE

Treated animals should not be handled or played with until the application site is dry. It is recommended that cats are treated during the early evening. Treated cats should not be allowed to sleep with owners, especially children.

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

This product can cause mucous membrane and eye irritation. Avoid getting the product on your skin, or in your mouth and eyes.

Wash off any product immediately with soap and water if skin contact occurs.

If the product gets in your eyes, 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 doctor.

If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the doctor.

Do not smoke, drink or eat during application. Wash hands after use.

Keep pipettes in original packaging until ready to use.

General precautions for Fiprotec Combo

Keep out of the sight and reach of children.

For animal treatment only.

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.

How should Fiprotec Combo be stored?

Store below 30 °C.

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

How should Fiprotec Combo be disposed?

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.

Available in cartons containing 1, 3 or 6 pipettes.

Not all pack sizes may be marketed.

Marketing authorisation holder:

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

Manufacturer for the batch release:

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

Date on which the package leaflet was last approved: November 2020.

Common PIL:

PACKAGE LEAFLET:

Fiprotec Combo 50 mg/60 mg spot-on solution for cats (UK)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Combo 50 mg/60 mg spot-on solution for cats (UK)
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)

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 (based on experimental data).
- Treatment of biting lice infestations (*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 to fipronil or S-methoprene or the other ingredients.

Do not apply on wounds or damaged skin.

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 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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cats

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

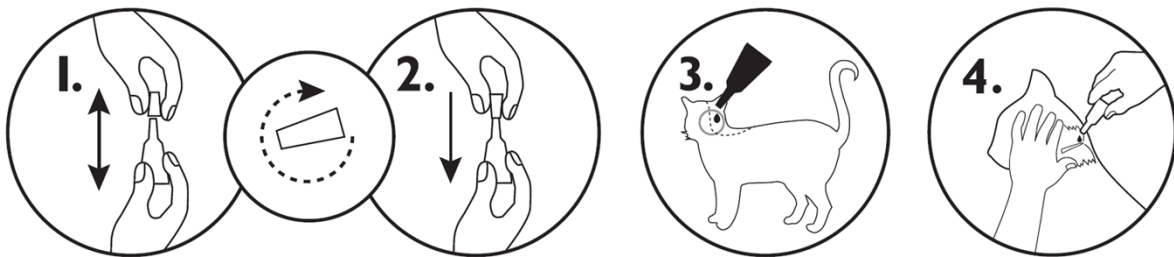
One pipette of 0.5 ml per cat weighing at least 1 kg corresponding to a minimum recommended dose of 5 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, by topical application to the skin.

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

9. ADVICE ON CORRECT ADMINISTRATION

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.
4. Part the coat 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.



10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 30 °C.

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.

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

Special precautions for use in animals:

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.

Do not overdose.

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 (allergy) to fipronil, S-methoprene, insecticides or alcohol 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. 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.

Pregnancy:

The product can be used during pregnancy.

Lactation:

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 (see section 4.6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

Incompatibilities:

None known.

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

November 2020.

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.

Approved: 18/03/21

