

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleascreen 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-methoprene (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?

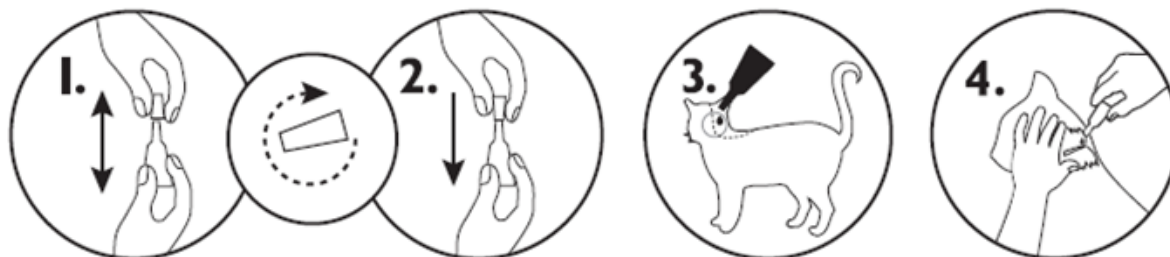
Kills fleas (*Ctenocephalides spp.*) on treated cats for up to 4 weeks and prevents eggs laid by exposed fleas from developing for up to 6 weeks. Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*) on treated cats for up to 2 weeks. Treats infestations with biting lice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

Read the package leaflet before use.

IS THIS PRODUCT SUITABLE FOR MY PET?

Only use Fleascreen 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 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.

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

Local representative:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156

16. MARKETING AUTHORISATION NUMBER

Vm 01656/4124

17. MANUFACTURER’S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleascreen 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

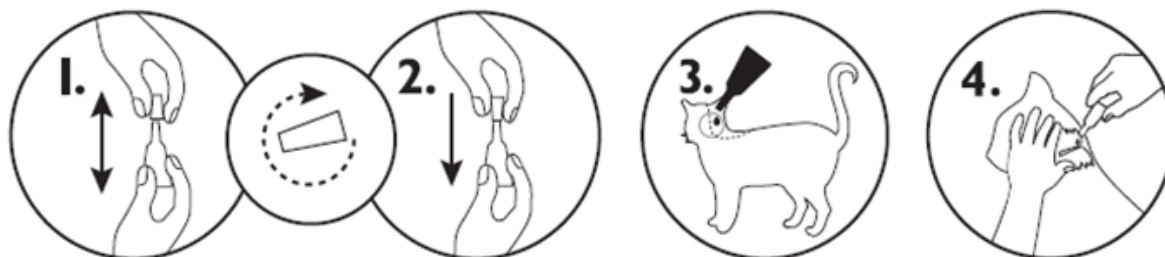
3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 x 0.5 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.
CATS & KITTENS

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

Fleascreen 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

Fleascreen Combo 50 mg/60 mg spot-on solution for cats Fipronil, S-Methoprene

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

What is Fleascreen Combo for?

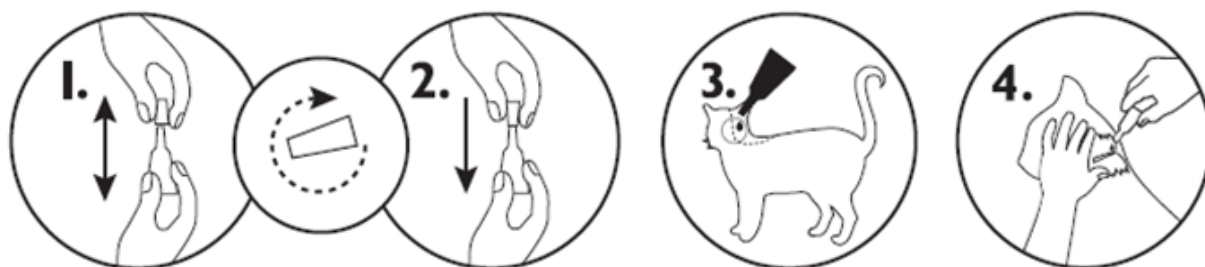
Fleascreen Combo spot-on solution for cats is used against infestations with fleas *Ctenocephalides* spp. (including their eggs and juvenile forms) and/or ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*) and/or biting lice (*Felicola subrostratus*).

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 Fleascreen 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.



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.

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 Fleascreen Combo?

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

Clear, yellow solution.

How often should I use Fleascreen 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 Fleascreen 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 Fleascreen 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 an allergy 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 Fleascreen Combo, even those not already listed in the package leaflet or you think that the medicine has not worked .

User safety with Fleascreen 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.

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.

People with a known hypersensitivity (allergy) to fipronil or the other ingredients should avoid contact with the product.

Keep pipettes in original packaging until ready to use.

General precautions for Fleascreen 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 Fleascreen Combo be stored?

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.

How should Fleascreen 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.

AVM-GSL

Vm 01656/4124

Marketing authorisation holder and manufacturer for the batch release:

KRKA, d.d., Novo mesto

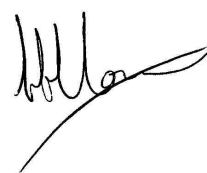
Šmarješka cesta 6

8501 Novo mesto

Slovenia

Date on which the package leaflet was last approved:

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

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

Approved 31 July 2019