

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleascreen Combo 268 mg/ 241.2 mg spot-on solution for large dogs
Fipronil, S-Methoprene

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

WHAT'S IN THIS PRODUCT?

Each pipette contains 268 mg Fipronil, 241.2 mg S-methoprene (active ingredients), 0.54 mg Butylhydroxyanisole (E320) and 0.27 mg Butylhydroxytoluene (E321).

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 x 2.68 ml

3 x 2.68 ml

6 x 2.68 ml

5. TARGET SPECIES

Dogs > 20-40 kg (dogs weighing over 20 kg and up to 40 kg)

6. INDICATION(S)

- Kills fleas, ticks and lice
- Protects for up to 8 weeks against fleas

WHAT DOES THIS PRODUCT DO?

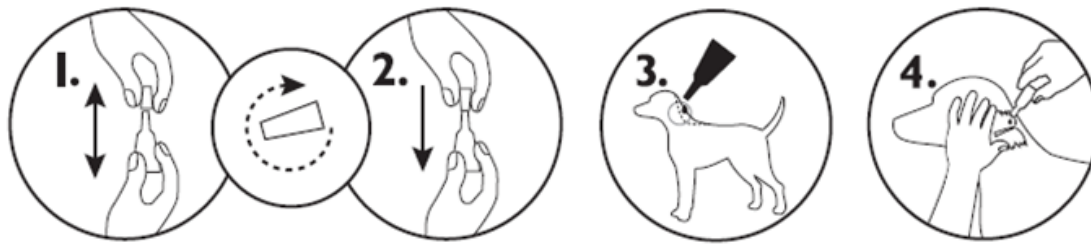
Kills fleas (*Ctenocephalides spp.*) on treated dogs and prevents eggs laid by exposed fleas from developing for up to 8 weeks. Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*) on treated dogs for up to 4 weeks. Treats infestations with biting lice (*Trichodectes canis*).

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 DOG?

Only use Fleascreen Combo if your dog is aged 8 weeks or older, and weighs more than 20 kg. Do not use if your dog is sick or recovering from an illness. Do not use if your dog has a hypersensitivity to fipronil or S-methoprene or the other ingredients. Do not apply on wounds or damaged skin. Do not use on cats. Do not use in rabbits, as adverse reactions including death, can 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.

As fipronil and S-methoprene may adversely affect aquatic organisms, dogs should not be allowed to swim in watercourses for 2 days after treatment.

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 01656/4127

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 268 mg/ 241.2 mg spot-on solution for large dogs
Fipronil, S-Methoprene

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each pipette contains 268 mg Fipronil, 241.2 mg S-methoprene

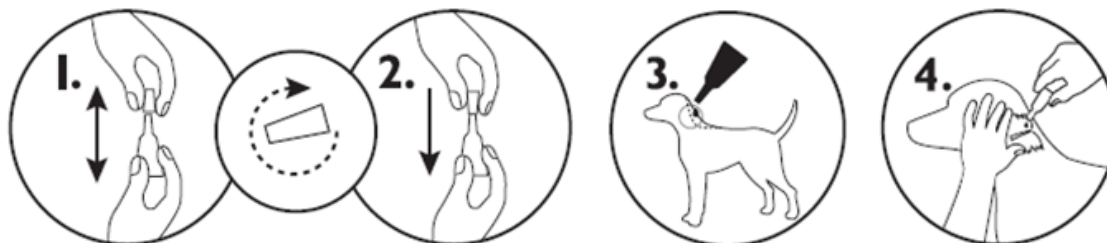
3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 x 2.68 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.
Large Dogs (20-40 kg)

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 268 mg/ 241.2 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 67 mg/60.3 mg spot-on solution for small dogs
Fleascreen Combo 134 mg/120.6 mg spot-on solution for medium dogs
Fleascreen Combo 268 mg/241.2 mg spot-on solution for large dogs
Fleascreen Combo 402 mg/361.8 mg spot-on solution for extra large dogs
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?

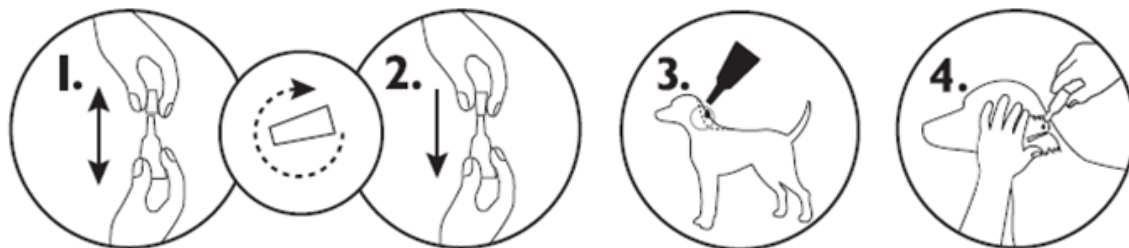
Fleascreen Combo spot-on solution for dogs is used against fleas *Ctenocephalides* spp. (including their eggs and juvenile forms), and/or ticks (*Ixodes ricinus*, *Dermacentor reticulatus* *Dermacentor variabilis*, *Rhipicephalus sanguineus*) and/or biting lice (*Trichodectes canis*) on dogs.

Efficacy against fleas and their multiplication lasts for up to 8 weeks. Efficacy against ticks lasts for up to 4 weeks.

How do I use Fleascreen Combo?

Animals should be weighed accurately prior to treatment.

One tube should be given to each dog, 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.

Make sure the product is applied to the skin in an area where the dog cannot lick and ensure that dogs do not lick each other after treatment. If dogs do lick the product, it can cause them to salivate (drool) for a brief period of time.

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

Bathing/immersion in water within 2 days after application of the product and more frequent bathing than once a week should be avoided. Emollient shampoos can be used prior to treatment, but reduce the duration of protection against fleas to approximately 5 weeks when used weekly after application of the product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study.

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

What size of Fleascreen Combo should be used?

Weigh the dog accurately before using the product to ensure the correct tube is used.

Dog weight (kg)	Fleascreen Combo	Treatment	Contents			
			Active substance		Other ingredients	
			Amount of fipronil	Amount of S-Methoprene	Butylhydroxy anisole (E320)	Butylhydroxytoluene (E321)
Over 2 – 10	67 mg for small dogs	1 tube of 0.67 ml	67 mg	60.30 mg	0.134 mg	0.067 mg
Over 10 – 20	134 mg for medium dogs	1 tube of 1.34 ml	134 mg	120.60 mg	0.27 mg	0.13 mg
Over 20 – 40	268 mg for large dogs	1 tube of 2.68 ml	268 mg	241.20 mg	0.54 mg	0.27 mg
Over 40 – 60	402 mg for extra large dogs	1 tube of 4.02 ml	402 mg	361.80 mg	0.80 mg	0.40 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 8 weeks and ticks are killed for up to 4 weeks. When a continued risk of flea infestation is anticipated the treatment can be repeated every 8 weeks or, when there is also a risk of tick infestation, 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 puppies less than 8 weeks old. .

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 dog has an allergy to fipronil, S-methoprene or the other ingredients.

Do not use in any other animal species, including cats and ferrets.

Do not apply on wounds or damaged skin.

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

Can be used in pregnant and nursing dogs.

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

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

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.

If the product gets in your eyes, immediately and thoroughly flush the eyes with water.

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

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.

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.

Fipronil and S-methoprene may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

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 product 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 pipetes.
Not all pack sizes may be marketed.

AVM-GSL

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 01 August 2019