

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleascreen 402 mg spot-on solution for extra large dogs
Fipronil

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 treatment (4.02 ml) contains:

Fipronil 402 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 treatment
3 treatments
6 treatments

5. TARGET SPECIES

Dogs (over 40 kg)

Suitable for breeds such as:
Bullmastif, Great Dane, Rottweiler, Irish Wolf Hound
Ensure dogs are weighed accurately before use

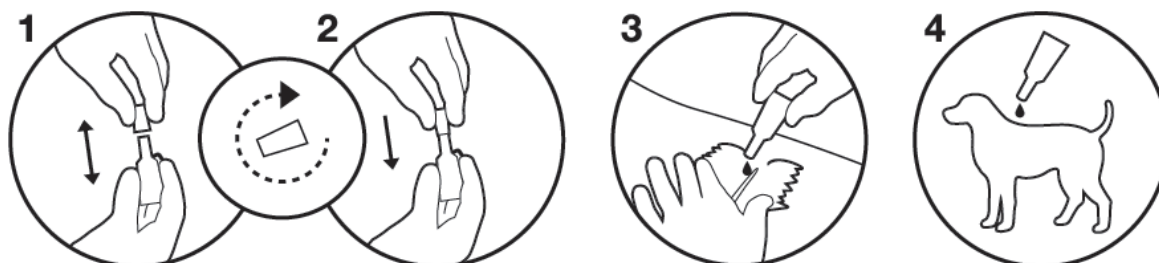
6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For spot-on use.

Read the package leaflet carefully for how to administer Fleascreen.
Administer 1 treatment of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight, or 1 treatment of 4.02 ml and an appropriate smaller treatment per dog weighing over 60 kg bodyweight.



8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use for full instructions and all warnings.
Keep in outer packaging and dispose of empty tubes immediately.
It is important that the user warnings are read before each use. Ensure that the package leaflet is kept in the outer carton.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Store in the original container in order to protect from light and moisture.
The product should be maintained at room temperature (above 14°C) for approximately one hour prior to administration.

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

Disposal: read the package leaflet.
Fipronil 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(S)

Vm 01656/4157

17. MANUFACTURER’S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleascreen 402 mg spot-on solution for extra large dogs
Fipronil

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil 402 mg

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

1 treatment of 4.02 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.
Dogs (over 40 kg)



5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

User warnings:

Treated animals should not be handled or played with until the application site is dry. It is recommended that dogs are treated during the early evening. Treated dogs 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 leaflet or this label to the doctor.

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

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleascreen 402 mg
Fipronil

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fipronil 402 mg

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

4.02 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Fleascreen for small, medium, large & extra large dogs

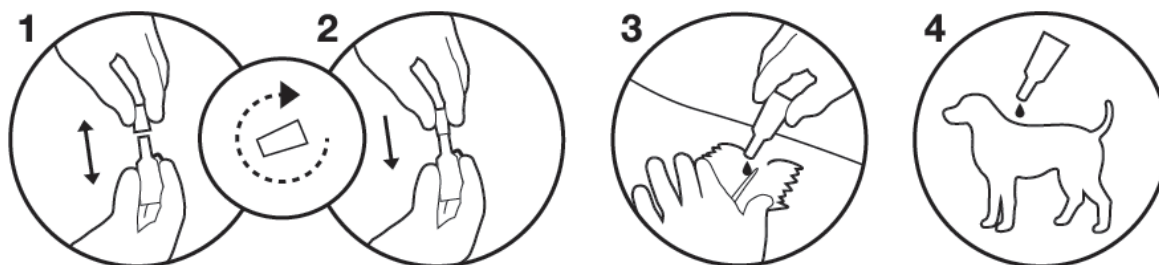
READ THIS INFORMATION CAREFULLY BEFORE EACH USE. KEEP THIS LEAFLET IN THE OUTER CARTON FOR FUTURE REFERENCE.

What is Fleascreen for?

Fleascreen spot-on solution for dogs is for killing fleas, ticks and lice on dogs. The product is applied on the skin between the shoulder blades, with each treatment lasting for up to 8 weeks (fleas) and 3 weeks (ticks). Most lice are killed within 2 days.

How do I use Fleascreen?

One tube should be given to each dog, applied to the skin as shown below. It is important that the correct tube is used for their weight, so weigh the dog before use.



1. Remove the tube from the foil bag. Hold in an upright position, twist and pull the cap off.
2. Turn the cap around and place the other end on the tube. Push and twist the cap to break the seal, then remove the cap.
3. Part the dog's hair between the shoulder blades.
4. Squeeze the tube and empty the contents directly onto the skin at one or two spots.

After treatment, you may notice a 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 or swimming should be avoided for 2 days after treatment. If weekly contact with water for one minute occurs, the treatment may only last for up to 7 weeks against fleas.

If ticks are present when the dog is treated, all ticks may not be killed within 48 hours.

This product will not stop ticks from attaching to your dog. If they attach after your dog has been treated, they will be killed within 24-48 hours. Dead ticks will often fall off your dog, but can be removed with a gentle pull.

What size of Fleascreen should be used?

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

Dog weight (kg)	Fleascreen	Treatment	Contents		
			Active substance	Other ingredients	
			Amount of fipronil	Butylhydroxyanisole (E320)	Butylhydroxytoluene (E321)
Over 2 – 10	67 mg for small dogs	1 tube of 0.67 ml	67 mg	0.134 mg	0.067 mg
Over 10 – 20	134 mg for medium dogs	1 tube of 1.34 ml	134 mg	0.268 mg	0.134 mg
Over 20 – 40	268 mg for large dogs	1 tube of 2.68 ml	268 mg	0.536 mg	0.268 mg
Over 40 – 60	402 mg for extra large dogs	1 tube of 4.02 ml	402 mg	0.804 mg	0.402 mg
Over 60	402 mg for extra large dogs AND the appropriate smaller tube	1 tube of 4.02 ml AND the appropriate smaller tube	402 mg AND the appropriate smaller tube	0.804 mg AND the appropriate smaller tube	0.402 mg AND the appropriate smaller tube

How often should I use Fleascreen?

Fleas are killed for up to 8 weeks and ticks for up to 3 weeks. The minimum treatment interval is 4 weeks.

Should I use anything else with Fleascreen?

All animals in the house should be treated with a suitable flea treatment. Fleas from cats and dogs can infest the animal's bedding or other areas in the house where they often go. Regular vacuuming and the use of a suitable household spray may be needed if there is a heavy infestation.

Animal safety with Fleascreen

Do not use on puppies less than 2 months old or weighing less than 2 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 dog has a hypersensitivity to fipronil or the other ingredients.

Do not apply on wounds or damaged skin.

Do not use in cats, as this may lead to overdosing.

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.
No specific studies have been performed in pregnant or nursing dogs. Therefore, speak to your veterinary surgeon before using Fleascreen in these situations.
Speak to your veterinary surgeon if you notice any adverse effects following the use of Fleascreen.

User safety with Fleascreen

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 dogs are treated during the early evening. Treated dogs 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.

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

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

General precautions for Fleascreen

Keep out of the sight and reach of children.

For animal treatment only.

For external use only.

Do not use after the expiry date.

How should Fleascreen be stored?

Store in the original carton to protect from light and moisture.

Keep the product at room temperature (above 14°C) for approximately one hour before treating your dog.

How should Fleascreen be disposed?

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after treatment. Do not contaminate ponds, waterways or ditches with the product or empty container. Dispose of empty packaging and any remaining product in the household refuse.

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

AVM-GSL

Fleascreen 67 mg spot-on solution for small dogs (Vm 01656/xxxx)

Fleascreen 134 mg spot-on solution for medium dogs (Vm 01656/xxxx)

Fleascreen 268 mg spot-on solution for large dogs (Vm 01656/xxxx)

Fleascreen 402 mg spot-on solution for extra large dogs (Vm 01656/xxxx)

Marketing authorisation holder and manufacturer responsible for batch release:

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

For further information on this product, please contact:

Local representative:

KRKA UK Ltd

United Kingdom

Tel: 02071 646 156

Date on which the package leaflet was last approved:

Approved: 17 December 2018

