A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleascreen 134 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

1 pipette (1.34 ml) contains:

Fipronil 134 mg

3. PACKAGE SIZE

1 pipette
3 pipettes
6 pipettes

4. TARGET SPECIES

Medium Dogs (10-20 kg)

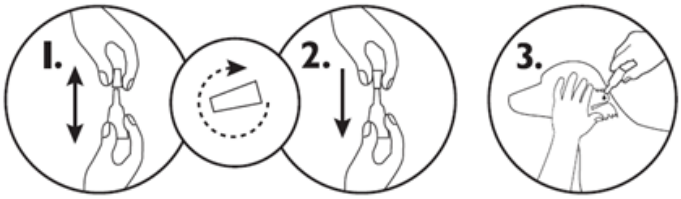
Suitable for breeds such as:
Springer Spaniel, Staffordshire Bull Terrier, Border Collie, Schnauzer
Ensure dogs are weighed accurately before use

5. INDICATIONS

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

6. ROUTES OF ADMINISTRATION

For spot-on use.
Read the package leaflet carefully for how to administer Fleascreen.
Administer 1 treatment of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight by topical application to the skin as follows:



7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

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 veterinary medicinal 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 veterinary medicinal 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.
Keep pipettes in the original packaging and dispose of used pipettes immediately.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/4155

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{SACHET}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleascreen

(10-20 kg)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

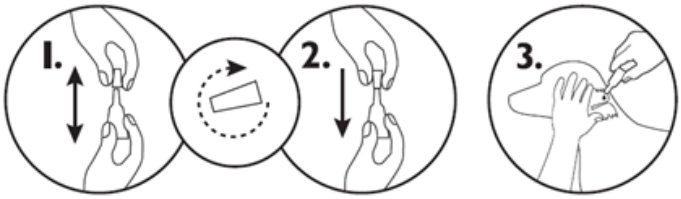
134 mg
fipronil

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}



MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{PIPETTE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleascreen

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

(10-20 kg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fleascreen 67 mg Spot-on Solution for Small Dogs
Fleascreen 134 mg Spot-on Solution for Medium Dogs
Fleascreen 268 mg Spot-on Solution for Large Dogs
Fleascreen 402 mg Spot-on Solution for Extra Large Dogs

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

2. Composition

What size of Fleascreen should be used?
Weigh the dog accurately before using the veterinary medicinal product to ensure the correct tube is used.
Each pipette contains:

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

Light yellow to yellow, clear liquid.

3. Target species

Dogs

4. Indications for use

What is Fleascreen for?
Fleascreen spot-on solution for dogs is for killing fleas, ticks and lice on dogs. The veterinary medicinal 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.

5. Contraindications

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.

6. Special warnings

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.
Dogs should not be allowed to swim in water courses for 2 days after treatment

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 veterinary medicinal product can cause mucous membrane and eye irritation. Avoid getting the veterinary medicinal product on your skin, or in your mouth and eyes.
Wash off any veterinary medicinal product immediately with soap and water if skin contact occurs.
If the veterinary medicinal 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 veterinary medicinal product.

General precautions for Fleascreen
For animal treatment only.
For external use only.

7. Adverse events

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

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 veterinary medicinal 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.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

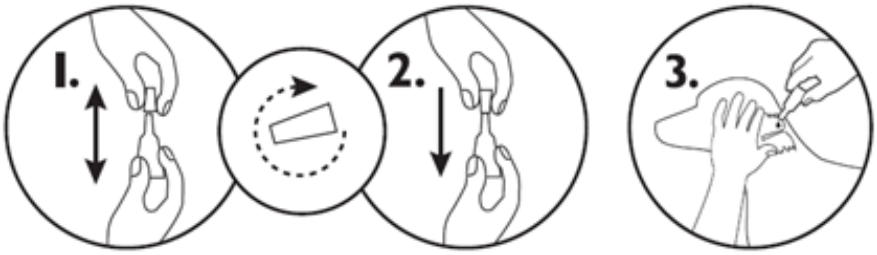
8. Dosage for each species, routes and method of administration

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.

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

9. Advice on correct administration

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. Squeeze the tube and empty the contents directly onto the skin at one or two spots.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

How should Fleascreen be stored?
Keep out of the sight and reach of children.
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.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the pipette after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

How should Fleascreen be disposed?

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as fipronil may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

Fleascreen 67 mg spot-on solution for small dogs (Vm 01656/4154)
Fleascreen 134 mg spot-on solution for medium dogs (Vm 01656/4155)
Fleascreen 268 mg spot-on solution for large dogs (Vm 01656/4156)
Fleascreen 402 mg spot-on solution for extra large dogs (Vm 01656/4157)

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

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
KRKA d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Local representatives and contact details to report suspected adverse reactions:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
info.uk@krka.biz

17. Other information

AVM-GSL

Approved 23 October 2025
Gavin Hall