A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RSPCA FleaAway 134 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1.34 ml pipette contains:

Fipronil 134 mg

3. PACKAGE SIZE

1 treatment
3 treatments
6 treatments

4. TARGET SPECIES

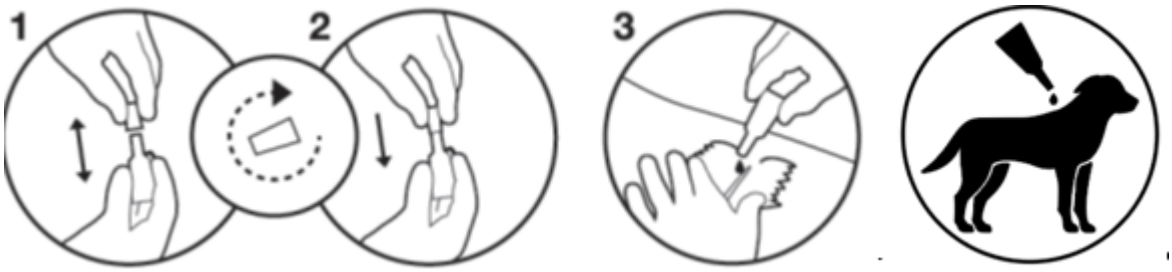
Dogs (10-20 kg)

5. INDICATIONS

- Kills fleas, ticks and lice
- Protects for up to 8 weeks against fleas and 3 weeks against ticks

6. ROUTES OF ADMINISTRATION

For spot-on use. Single dose pipette.
Read the package leaflet carefully for how to administer RSPCA FleaAway.
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:



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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 for full instructions and warnings.
Prevent children getting access to the pipettes.
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.

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 NUMBER

Vm 01656/4079

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{SACHET}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RSPCA FleaAway

10-20 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

134 mg
fipronil

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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 veterinary medicinal 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 irritation persists or the product is accidentally swallowed seek medical advice and show the leaflet or the label to the physician.
Do not smoke, drink or eat during application. Wash hands after use.
People who are allergic to fipronil or dimethyl sulfoxide or the other ingredients should avoid contact with the veterinary medicinal product.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{PIPETTE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RSPCA FleaAway

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10-20 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

RSPCA FleaAway 67 mg spot-on solution for small dogs
RSPCA FleaAway 134 mg spot-on solution for medium dogs
RSPCA FleaAway 268 mg spot-on solution for large dogs
RSPCA FleaAway 402 mg spot-on solution for extra large dogs

2. Composition

What size of RSPCA FleaAway should be used?
Weigh the dog accurately before using the veterinary medicinal product to ensure the correct tube is used.

Dog weight (kg)	**RSPCA FleaAway**	**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 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

Light yellow to yellow, clear liquid.

3. Target species

Dogs

4. Indications for use

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

What is RSPCA FleaAway for?
RSPCA FleaAway 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

Animal safety with RSPCA FleaAway
Do not use on puppies less than 2 months old or weighing less than 2 kg.
Do not use on rabbits as adverse reactions, or even death, could occur.
Do not use on sick or convalescent animals.

Do not use if your dog is known to be allergic to the active substance (fipronil) or to any of the other ingredients (excipients).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 RSPCA FleaAway in these situations.
Speak to your veterinary surgeon if you notice any adverse effects following the use of RSPCA FleaAway.

6. Special warnings

User safety with RSPCA FleaAway
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 physician.
Do not smoke, drink or eat during application. Wash hands after use.
People with a known hypersensitivity to fipronil or dimethyl sulfoxide or the other ingredients should avoid contact with the veterinary medicinal product.
Ingestion of the veterinary medicinal product is harmful. Prevent children getting access to the pipettes. Keep pipettes in the original packaging and discard the used pipettes immediately after applying the veterinary medicinal product. If any of the veterinary medicinal product is swallowed, seek medical advice immediately.

Should I use anything else with RSPCA FleaAway?
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.

7. Adverse events

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

Make sure the veterinary medicinal 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 veterinary medicinal product, it can cause them to salivate (drool) for a brief period of time.

In very rare cases (<1 animal / 10,000 animals treated, including isolated reports), redness or discolouration of the skin, hair loss and itching may occur at the treatment site or on the dog in general. Excess salivation, reversible nervous signs (increased sensitivity to stimulation,depression, other nervous signs), vomiting or breathing problems have also been observed very rarely after use.

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.

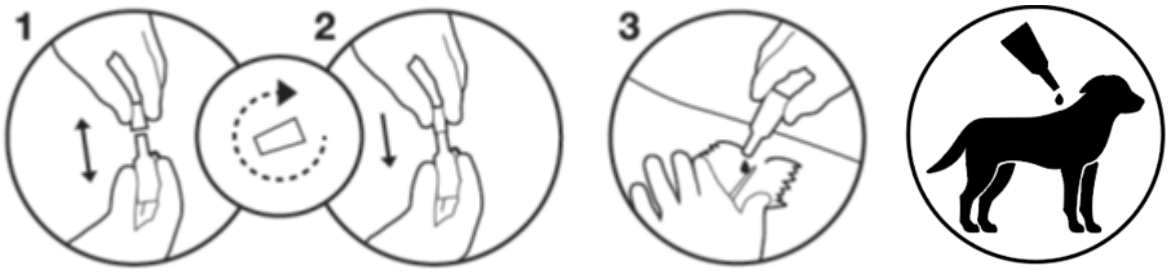
If ticks are present when the dog is treated, all ticks may not be killed within 48 hours. This veterinary medicinal product will not stop ticks from attaching to your dog. If they attach after your dog has been treated, they will be killed within 24-48 hours. Dead ticks will often fall off your dog,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

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

How often should I use RSPCA FleaAway?
Fleas are killed for up to 8 weeks and ticks for up to 3 weeks. The minimum treatment interval is 4 weeks.

9. Advice on correct administration

How do I use RSPCA FleaAway?
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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

General precautions for RSPCA FleaAway
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 RSPCA FleaAway be stored?
Store in the original carton to protect from light and moisture.
Keep the veterinary medicinal product at room temperature (above 14°C) for approximately one hour before treating your dog.

12. Special precautions for disposal

How should RSPCA FleaAway 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.

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

RSPCA FleaAway 67 mg spot-on solution for small dogs (Vm 01656/4078)
RSPCA FleaAway 134 mg spot-on solution for medium dogs (Vm 01656/4079)
RSPCA FleaAway 268 mg spot-on solution for large dogs (Vm 01656/4080)
RSPCA FleaAway 402 mg spot-on solution for extra large dogs (Vm 01656/4081)

White polypropylene pipette closed with either a polyethylene or polyoxymethylene cap. Each pipette is packed in a polyethylene terephthalate/aluminium/low density polyethylene triplex bag.
Box 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 for the batch release:
KRKA, d.d., Novo mesto
Smarjeska 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 12 August 2026
Gavin Hall