PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RSPCA FLEAaway Combo 268 mg/241.2 mg Spot-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

WHAT'S IN THIS PRODUCT?
Each 2.68 ml pipette contains:
Active substance:

Fipronil	268 mg
S-Methoprene	241.2 mg

3. PACKAGE SIZE

1 x 2.68 ml
3 x 2.68 ml
6 x 2.68 ml

4. TARGET SPECIES

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

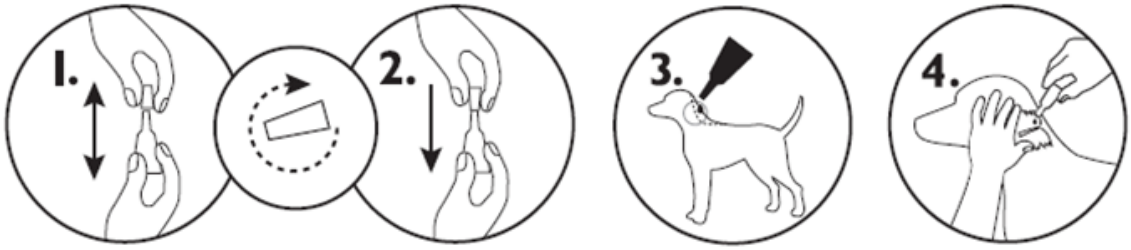
5. INDICATION(S)

- 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*).

6. ROUTES OF ADMINISTRATION

How to apply this product



1 x Treatment
For external use only.

HOW DO I USE THIS PRODUCT?
Before use, read the package leaflet for full instructions and all warnings, including user warnings.
1. Hold pipette upright. Twist and pull cap off.
2. Use the tip of cap to break seal.
3. Part the coat on the back of the animal until the skin is visible
4. Apply pipette to one spot of the skin and squeeze to empty.
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.

7. WITHDRAWAL PERIOD

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

HOW SHOULD I STORE THE PRODUCT
Store in the original package in order to protect from light and moisture.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

IS THIS PRODUCT SUITABLE FOR MY DOG?
Only use RSPCA FLEAaway Combo 268 mg/ 241.2 mg 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 (allergy) to fipronil or S-methoprene or the other ingredients.
Do not apply on wounds or damaged skin.

Do not use in any other animal species, only use on dogs. Do not use on cats.
Do not use in rabbits as adverse drug reactions, including death, may occur.

USER SAFETY- Please read before every use.
This veterinary medicinal product can cause mucous membrane, skin and eye irritation. Therefore, contact of the veterinary medicinal product with mouth, skin and eyes should be avoided.
People with a known hypersensitivity (allergy) to fipronil, S-methoprene, or alcohol should avoid contact with the veterinary medicinal product. Avoid contents coming into contact with the fingers. If the veterinary medicinal product comes into contact with fingers, wash hands with soap and water. After accidental eye contact, rinse carefully in clean water. If the veterinary medicinal product is accidentally swallowed,

seek medical advice immediately and show the package leaflet or the label 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 and dispose of used pipettes immediately.

Special precautions for the protection of the environment:
As fipronil and S-methoprene may adversely affect aquatic organisms, dogs should not be allowed to swim in watercourses for 2 days after treatment.

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, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/3011
Vm 01656/5011

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{ BAG }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RSPCA FLEAaway Combo

20-40 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fipronil/ S-methoprene
268 mg/241.2 mg

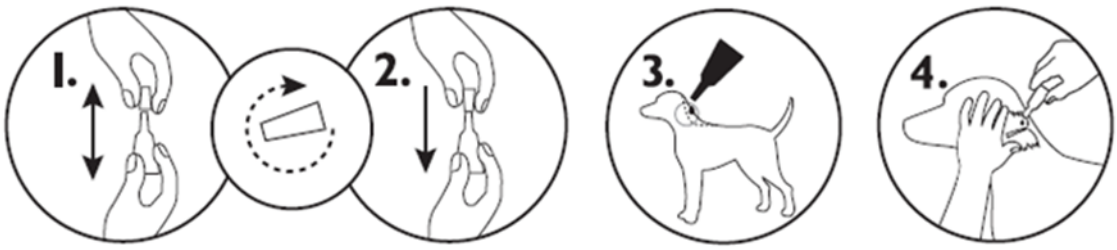
3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Marketing authorisation holder
KRKA



MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{ PIPETTE }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RSPCA FLEAaway Combo

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

20 – 40 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 Combo 67 mg/60.3 mg Spot-on Solution for Small Dogs
RSPCA FLEAaway Combo 134 mg/120.6 mg Spot-on Solution for Medium Dogs
RSPCA FLEAaway Combo 268 mg/241.2 mg Spot-on Solution for Large Dogs
RSPCA FLEAaway Combo 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs

2. Composition

Each 0.67 ml pipette contains:
Active substance:

Fipronil	67 mg
S-Methoprene	60.30 mg

Excipients:

Butylhydroxyanisole (E320)	0.134 mg
Butylhydroxytoluene (E321)	0.067 mg

Each 1.34 ml pipette contains:
Active substance:

Fipronil	134 mg
S-Methoprene	120.60 mg

Excipients:

Butylhydroxyanisole (E320)	0.27 mg
Butylhydroxytoluene (E321)	0.13 mg

Each 2.68 ml pipette contains:
Active substance:

Fipronil	268 mg
S-Methoprene	241.20 mg

Excipients:

Butylhydroxyanisole (E320)	0.54 mg
Butylhydroxytoluene (E321)	0.27 mg

Each 4.02 ml pipette contains:
Active substance:

Fipronil	402 mg
S-Methoprene	361.80 mg

Excipients:

Butylhydroxyanisole (E320)	0.80 mg
Butylhydroxytoluene (E321)	0.40 mg

Clear yellow solution.

3. Target species

Dogs.

4. Indications for use

To be used against infestations with fleas, alone or in association with ticks and/or biting lice.
Treatment of flea infestations (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity) and larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for eight weeks after application.
Treatment of tick infestations (*Ixodes ricinus, Dermacentor variabilis, Dermacentor reticulatus, Rhipicephalus sanguineus*). The product has persistent acaricidal efficacy for up to 4 weeks against ticks.
Treatment of infestations with biting lice (*Trichodectes canis*).

5. Contraindications

Do not use on puppies less than 8 weeks old.
Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.
Do not use if your dog has a hypersensitivity (allergy) to fipronil or S-methoprene or the other ingredients.
Do not apply on wounds or damaged skin.
Do not use in any other animal species, only use on dogs. Do not use in cats and ferrets, as this could lead to overdosing.
Do not use in rabbits as adverse drug reactions, including death, may occur.

6. Special warnings

Special warnings:
Bathing/immersion in water within 2 days after application of the product and more frequent bathing than once a week should be avoided, as no study has been performed to investigate how this affects the efficacy of the product. 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.
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.

Special precautions for safe use in the target species:
Avoid contact with the animal's eyes.
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.
Dogs should not be allowed to swim in watercourses for 2 days after application.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This veterinary medicinal product can cause mucous membrane, skin and eye irritation. Therefore, contact of the veterinary medicinal product with mouth, skin and eyes should be avoided.
People with a known hypersensitivity (allergy) to fipronil S-methoprene, or alcohol should avoid contact with the veterinary medicinal product. Avoid contents coming into contact with the fingers. If the veterinary medicinal product comes into contact with the fingers, wash hands with soap and water.
After accidental eye contact, be rinse carefully with clean water.
If the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label 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 and dispose of used pipettes immediately.

Special precautions for the protection of the environment:
As fipronil and S-methoprene may adversely affect aquatic organisms, dogs should not be allowed to swim in watercourses for 2 days after treatment.

Pregnancy and lactation:
The product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with other flea products which are applied directly on to the animal.

Overdose:
No adverse effects were observed in target animal safety studies in 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated once at five times the recommended dose. The risk of experiencing adverse effects (see section 6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

7. Adverse events

Dog:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site skin discoloration, hair loss, itching, reddening* Generalised itching or hair loss
Undetermined frequency (cannot be estimated from the available data)	Increased salivation Vomiting Increased sensitivity to stimulation, depression, other nervous signs Respiratory signs

*Transient.

In the case of licking the administration site, a brief period of excessive salivation may be observed due mainly to the nature of the carrier.

Do not overdose.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medical 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 its local representative using the contact details at the end of this leaflet, or via your national reporting system:
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

Route of administration and dosage:
External use only.

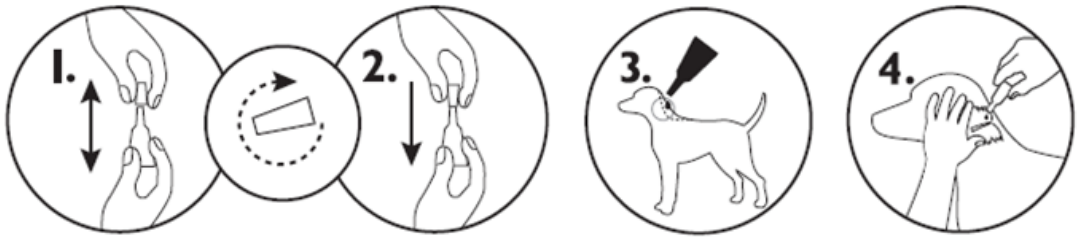
For spot-on administration. Apply one pipette per dog by topical application to the skin according to the bodyweight as follows:

Dogs	**Number of pipettes**	**Pipette volume**	**Potency (fipronil + (S)-methoprene**
over 2 kg and up to 10 kg	1 pipette	0.67 ml	67 mg + 60.3 mg
over 10 kg and up to 20 kg	1 pipette	1.34 ml	134 mg + 120.6 mg
over 20 kg and up to 40 kg	1 pipette	2.68 ml	268 mg + 241.2 mg
over 40 kg and up to 60 kg	1 pipette	4.02 ml	402 mg + 361.8 mg

This corresponds to a minimum recommended dose of 6.7 mg/kg for fipronil and 6 mg/kg for S-methoprene, by topical application to the skin.

Method of administration:

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.
4. 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.



Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

9. Advice on correct administration

In the absence of safety studies the minimum treatment interval is 4 weeks.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as Fipronil and S-methoprene 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.

Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty container.

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

Vm 01656/5009
Vm 01656/3009
Vm 01656/5010
Vm 01656/3010
Vm 01656/5011
Vm 01656/3011
Vm 01656/5012
Vm 01656/3012

Cardboard 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 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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

AVM-GSL

Gavin Hall

Approved: 16 June 2026