

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RSPCA FLEAaway Combo 50 mg/60 mg Spot-on Solution for Cats
Fipronil, S-methoprene

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

WHAT'S IN THIS PRODUCT?

Each 0.5 ml pipette contains:

Active substances:

50 mg fipronil
60 mg S-methoprene

Excipients:

0.1 mg Butylhydroxyanisole (E320)
0.05 mg Butylhydroxytoluene (E321)

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 x 0.5 ml
3 x 0.5 ml
6 x 0.5 ml

5. TARGET SPECIES

CATS

6. INDICATION(S)

- Kills fleas, ticks and lice
- Protects for up to 4 weeks against fleas

WHAT DOES THIS PRODUCT DO?

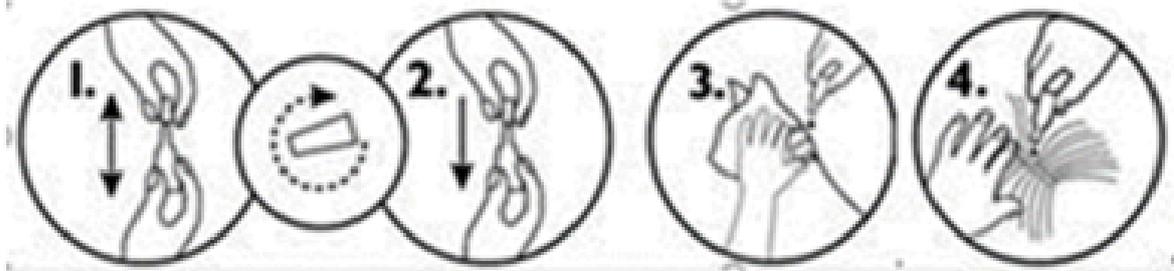
Kills fleas (*Ctenocephalides spp.*) on treated cats for up to 4 weeks and prevents eggs laid by exposed fleas from developing for up to 6 weeks. Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*) on treated cats for up to 2 weeks. Treats infestations with biting lice (*Felicola subrostratus*).

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.

1. Hold the pipette upright. Twist and pull the cap off.
2. Use the tip of the pipette to break the pipette's seal.
3. Part the coat on the back of the animal's neck in front of the shoulder blades until the skin is visible.
4. Apply the pipette to the skin and squeeze it several times to empty all of its contents 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

For external use only.

Read the package leaflet before use.

IS THIS PRODUCT SUITABLE FOR MY PET?

Only use this product if your cat is at least 8 weeks old and weighs more than 1 kg. Do not use if your pet is sick or recovering from an illness. Do not use if your pet has a hypersensitivity (allergy) to fipronil or S-methoprene or the other ingredients. Do not apply on wounds or damaged skin.

Only use on cats, do not use in any other animal species.

Do not use on rabbits as adverse drug reactions, including death, may 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 fipronil, S-methoprene, or alcohol should avoid contact with the product. Avoid contents coming into contact with the fingers. If the product comes into contact with fingers, wash hands with soap and water. After accidental eye contact, rinse carefully in clean water. If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label 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 and dispose of used pipettes immediately.

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

Fipronil and S-methoprene may adversely affect aquatic organisms. Dispose of empty packaging and any remaining product in the household refuse.

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

16. MARKETING AUTHORISATION NUMBER

Vm 01656/5008

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RSPCA FLEAaway Combo 50 mg/60 mg Spot-on Solution for Cats
Fipronil, S-methoprene

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each pipette contains 50 mg fipronil, 60 mg S-methoprene

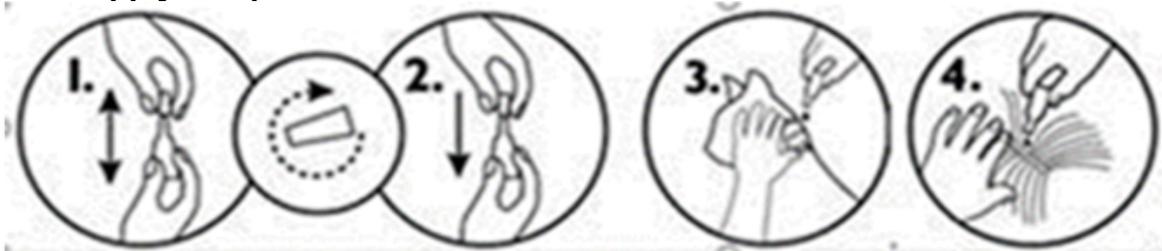
3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 x 0.5 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.
CATS & KITTENS

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

RSPCA FLEAaway Combo 50 mg/60 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 FOR:

RSPCA FLEAaway Combo 50 mg/60 mg Spot-on Solution for Cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RSPCA FLEAaway Combo 50 mg/60 mg Spot-on Solution for Cats
Fipronil, S-methoprene

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each 0.5 ml pipette contains:

Active substances:

Fipronil	50 mg
S-methoprene	60 mg

Excipients:

Butylhydroxyanisole (E320)	0.1 mg
Butylhydroxytoluene (E321)	0.05 mg

4. INDICATION(S)

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 4 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for six weeks after application.
- Treatment of tick infestations (*Ixodes ricinus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 2 weeks against ticks.
- Treatment of infestations with biting lice (*Felicola subrostratus*).

5. CONTRAINDICATIONS

Do not use on kittens less than 8 weeks old and/or weighing less than 1 kg.
Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.
Do not use if your cat has a hypersensitivity (allergy) to fipronil or S-methoprene or the other ingredients.
Only use in cats, do not use in any other animal species.

Do not use on rabbits as adverse drug reactions, including death, may occur.

6. ADVERSE REACTIONS

Do not overdose.

Cat:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site skin scaling, 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

*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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 using the contact details at the end of this leaflet, or via your national reporting system (<https://www.gov.uk/report-veterinary-medicine-problem>).

7. TARGET SPECIES

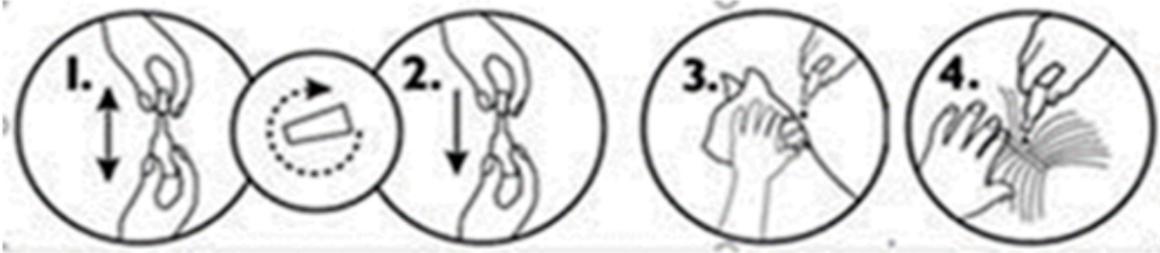
Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For spot-on administration. Apply one pipette of 0.5 ml per cat by topical application to the skin, corresponding to a minimum recommended dose of 5 mg/kg for fipronil and 6 mg/kg for S-methoprene.

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.



9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

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.

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the box after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

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.

Bathing and/or shampooing should be avoided. No information on the effect of bathing or the use of a shampoo on the effectiveness of the product in cats is available. Based on information available for dogs, bathing/immersion in water within 2 days after application of the product and more frequent bathing than once a week should be avoided.

Special precautions for use in animals:

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.

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

The potential toxicity of the product for kittens of less than 8 weeks of age in contact with a treated queen is not documented. Special care should be taken in this case.

User Warnings:

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 fipronil, S-methoprene, or alcohol should avoid contact with the product. Avoid contents coming into contact with the fingers. If the product comes into contact with fingers, wash hands with soap and water.

After accidental eye contact, rinse carefully with clean water.

If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label 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 and dispose of used pipettes immediately.

Pregnancy and lactation:

The product can be used during pregnancy.

The potential toxicity of the product for kittens of less than 8 weeks of age in contact with a treated queen is not documented. Special care should be taken in this case.

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 (symptoms, emergency procedures, antidotes):

No undesirable effects were observed in target animal safety studies in cats and kittens aged 8 weeks and older and weighing about 1 kg treated once a month at five times the recommended dose for six consecutive months.

Itching may occur following treatment.

Overdose application of the product will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

The risk of experiencing adverse effects may increase with overdosing (see section 6 Adverse reactions).

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

Medicines should not be disposed of via wastewater.

Fipronil and S-methoprene should not enter water courses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

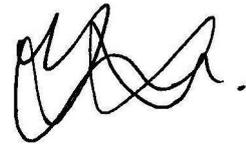
September 2023

15. OTHER INFORMATION

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

AVM-GSL

For Animal Treatment Only

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 14 September 2023