PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Combo 402 mg/ 361.8 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

WHAT'S IN THIS PRODUCT?
Each 4.02 ml pipette contains:

fipronil	402 mg
s-methoprene	361.8 mg

3. PACKAGE SIZE

1 x 4.02 ml
3 x 4.02 ml
6 x 4.02 ml

4. TARGET SPECIES

Dogs > 40 kg

5. INDICATIONS

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*).

Ixodida

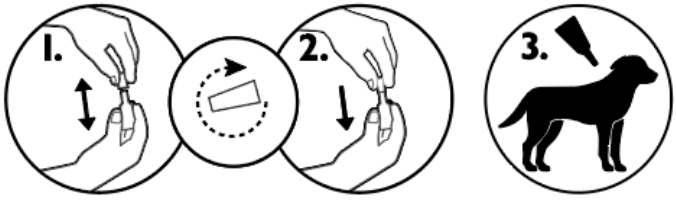
Ctenocephalides felis

Trichodectes canis

6. ROUTES OF ADMINISTRATION

Spot-on solution.

How to apply this product



1 x Treatment

HOW DO I USE THIS PRODUCT?

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. 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.

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 PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

HOW SHOULD I STORE AND DISPOSE OF THE PRODUCT
Store below 30 °C.
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.

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, insecticides or alcohol should avoid contact with the veterinary medicinal product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.
After accidental ocular exposure the eye should be rinsed carefully in clean water.
If the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet 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.

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 01656/4121

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Combo

> 40 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

fipronil /s-methoprene
402 mg/ 361.8 mg

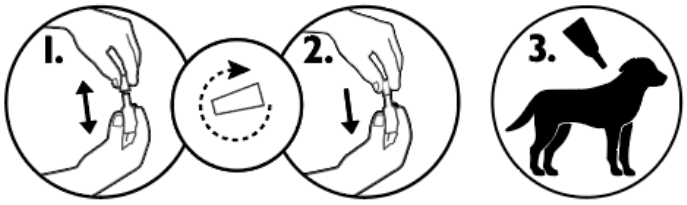
3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {mm/yyyy}

Marketing authorisation holder
KRKA



MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{PIPETTA}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Combo

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

> 40 kg

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fiprotec Combo 67 mg/60.3 mg spot-on solution for small dogs
Fiprotec Combo 134 mg/120.6 mg spot-on solution for medium dogs
Fiprotec Combo 268 mg/241.2 mg spot-on solution for large dogs
Fiprotec Combo 402 mg/361.8 mg spot-on solution for extra large dogs

2. Composition

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

Dog weight (kg)	**Fiprotec Combo**	**Treatment**	**Contents**			
			Active substance		Other ingredients	
			Amount of fipronil	Amount of S-Methoprene	Butylhydroxyanisole (E320)	Butylhydroxytoluene (E321)
Over 2 – 10	67 mg for small dogs	1 tube of 0.67 ml	67 mg	60.30 mg	0.134 mg	0.067 mg
Over 10 – 20	134 mg for medium dogs	1 tube of 1.34 ml	134 mg	120.60 mg	0.27 mg	0.13 mg
Over 20 – 40	268 mg for large dogs	1 tube of 2.68 ml	268 mg	241.20 mg	0.54 mg	0.27 mg
Over 40 – 60	402 mg for extra large dogs	1 tube of 4.02 ml	402 mg	361.80 mg	0.80 mg	0.40 mg

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 Fiprotec Combo for?
Fiprotec Combo spot-on solution for dogs is used against fleas *Ctenocephalides* spp. (including their eggs and juvenile forms), and/or ticks (*Ixodes ricinus, Dermacentor reticulatus Dermacentor variabilis, Rhipicephalus sanguineus*) and/or biting lice (*Trichodectes canis*) on dogs.
Efficacy against fleas and their multiplication lasts for up to 8 weeks. Efficacy against ticks lasts for up to 4 weeks.

5. Contraindications

Animal safety with Fiprotec Combo

Do not use on puppies less than 8 weeks 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 S-methoprene or the other ingredients.
Do not use in any other animal species, including cats and ferrets.
Do not apply on wounds or damaged skin.
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 Fiprotec Combo in these situations.
Speak to your veterinary surgeon if you notice any adverse effects following the use of Fiprotec Combo, even those not already listed in the package leaflet or you think that the medicine has not worked.

6. Special warnings

User safety with Fiprotec Combo

PLEASE READ THESE WARNINGS BEFORE EACH USE
This product can cause mucous membrane, skin and eye irritation. Avoid getting the product on your skin, or in your mouth and eyes.
People with a known hypersensitivity (allergy) to fipronil, S-methoprene, insecticides or alcohol should avoid contact with the veterinary medicinal product.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.
If the veterinary medicinal product gets in your eyes, immediately and thoroughly flush the eyes with water.
If the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet 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.

Should I use anything else with Fiprotec Combo?

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.
Do not use simultaneously with other flea products which are applied directly on to the animal.

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 water courses for 2 days after treatment.

7. Adverse events

After treatment, you may notice transient 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 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/immersion in water within 2 days after application of the veterinary medicinal product and more frequent bathing than once a week should be avoided. 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 veterinary medicinal product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study.

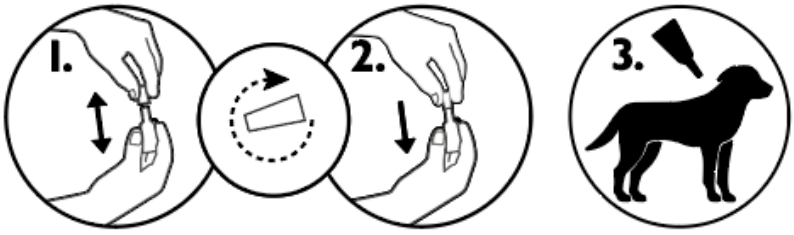
There may be an attachment of a few ticks. For this reason, a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

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

How often should I use Fiprotec Combo?
Always leave a minimum period of 4 weeks between treatments. Adult fleas are killed for up to 8 weeks and ticks are killed for up to 4 weeks. When a continued risk of flea infestation is anticipated the treatment can be repeated every 8 weeks or, when there is also a risk of tick infestation, the treatment can be repeated every 4 weeks.

9. Advice on correct administration

How do I use Fiprotec Combo?
Animals should be weighed accurately prior to treatment; do not use in puppies weighing less than 2 kg.
One tube should be given to each dog, applied to the skin as shown below.



Remove the pipette from its packaging. Hold the pipette in an upright position, twist and pull the cap off.

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.
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. 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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

General precautions for Fiprotec Combo
Keep out of the sight and reach of children.
For animal treatment only.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after {Exp.}. The expiry date refers to the last day of that month.

How should Fiprotec Combo be stored?
Store below 30 °C.
Store in the original package in order to protect from light and moisture.

12. Special precautions for disposal

How should Fiprotec Combo be disposed?
Medicines should not be disposed of via wastewater.
The veterinary medicinal product should not enter water courses as Fipronil and (S) methoprene 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

14. Marketing authorisation numbers and pack sizes

Vm 01656/4119
Vm 01656/4120
Vm 01656/4121
Vm 01656/4123

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 for the 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: 14 October 2025