

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Combo 402 mg/ 361.8 mg spot-on solution for extra large dogs (UK)
Fipronil, S-Methoprene

2. STATEMENT OF ACTIVE SUBSTANCES

WHAT'S IN THIS PRODUCT?

Each pipette contains 402 mg Fipronil, 361.8 mg S-methoprene (active ingredients).

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs >40 kg (dogs weighing over 40 kg)

6. INDICATION(S)

For OTC products

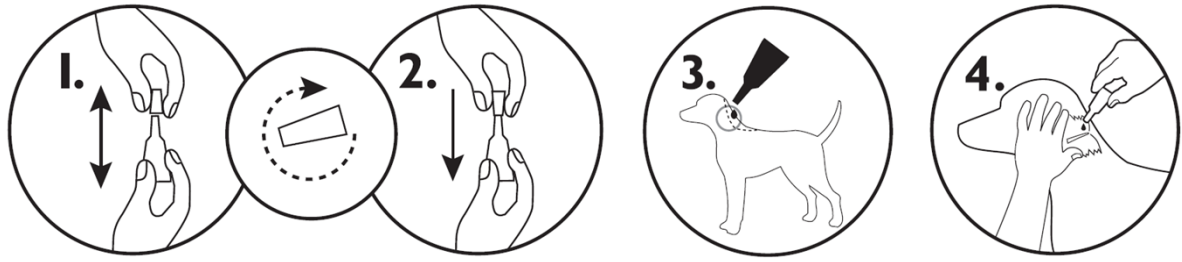
WHAT DOES THIS PRODUCT DO?

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*).

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. 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. Apply to the skin at the base of the neck in front of the shoulder blades. Part the coat 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.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

IS THIS PRODUCT SUITABLE FOR MY DOG?

Only use Fiprotec **Amflee** Combo if your dog is aged 8 weeks or older, and weighs over 40 kg. Do not use if your dog is sick or recovering from an illness. Do not use if your dog has a hypersensitivity to fipronil or S-methoprene or the other ingredients. Do not apply on wounds or damaged skin. Do not use on cats. Do not use in rabbits, as adverse reactions including death, can 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, 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 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.

Fipronil and S-methoprene may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

HOW SHOULD I STORE AND DISPOSE OF THE PRODUCT

Dispose of waste material in accordance with local requirements. Fipronil and S-methoprene may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

Only for those countries where the product is available on prescription:

To be supplied only on veterinary prescription.

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(S)

Vm 01656/4121

17. MANUFACTURER’S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{ BAG }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fiprotec Combo 402 mg/ 361.8 mg spot-on solution for extra large dogs (UK)
Fipronil, S-Methoprene

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each pipette contains 402 mg Fipronil, 361.8 mg S-methoprene

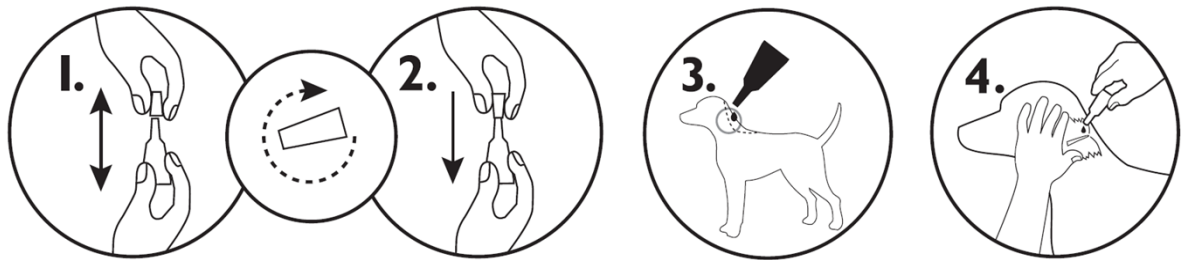
3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 x 4.02 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.
Dogs >40 kg (dogs weighing over 40 kg)

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

Fiprotec Combo 402 mg/ 361.8 mg (UK)
Fipronil, S-Methoprene

2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

National PIL UK

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

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

What is Fiprotec Combo for?

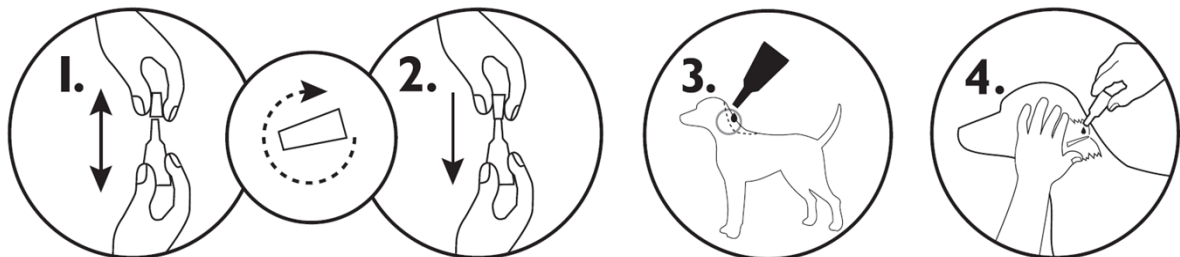
Fiprotec Combo spot-on solution for dogs is used against fleas *Ctenocephalides* spp. (including their eggs and juvenile forms), and/or ticks (*Ixodes ricinus*, *Dermacentor reticulatus* *Dermacentor variabilis*, *Rhipicephalus sanguineus*) and/or biting lice (*Trichodectes canis*) on dogs.

Efficacy against fleas and their multiplication lasts for up to 8 weeks. Efficacy against ticks lasts for up to 4 weeks.

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.

Apply to the skin at the base of the neck in front of the shoulder blades.

Part the coat 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.

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

Make sure the 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 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 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 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.

What size of Fiprotec Combo should be used?

Weigh the dog accurately before using the 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

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.

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.

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.

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 product gets in your eyes, immediately and thoroughly flush the eyes with water.

If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet 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.

General precautions for Fiprotec Combo

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.

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.

How should Fiprotec Combo be disposed?

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Do not contaminate ponds, waterways or ditches with the product or empty container.

Available in cartons containing 1, 3 or 6 pipetes.

Not all pack sizes may be marketed.

Marketing authorisation holder:

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

Manufacturer for the batch release:

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

Date on which the package leaflet was last approved: November 2020

Common PIL

PACKAGE LEAFLET:

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
(UK)

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

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

2. 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
(UK)

Fipronil, S-Methoprene

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

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.

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 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

In the absence of available data, the product should not be used on puppies less than 8 weeks old and/or weighing less than 2 kg.

Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.

Do not use if your dog has a hypersensitivity to fipronil or S-methoprene or the other ingredients.

Do not apply on wounds or damaged skin.

Do not use in cats and ferrets, as this could lead to overdosing.

Do not use in rabbits, as adverse reactions with even mortality could occur.

Do not use in any other non-target species.

6. ADVERSE REACTIONS

Among the very rare suspected adverse reactions, transient skin reactions on the application site (skin discoloration, local hair loss, itching, redness) and general

itching or hair loss have been reported after use. Excessive salivation, reversible nervous signs (increased sensitivity to stimulation, depression, other nervous signs), vomiting or respiratory symptoms have also been observed after use.

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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

- Dogs >2-10 kg (dogs weighing over 2 kg and up to 10 kg)
- Dogs >10-20 kg (dogs weighing over 10 kg and up to 20 kg)
- Dogs >20-40 kg (dogs weighing over 20 kg and up to 40 kg)
- Dogs >40 kg (dogs weighing over 40 kg)

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

Route of administration and dosage:

External use only.

Dogs >2-10 kg (dogs weighing over 2 kg and up to 10 kg)

One pipette of 0.67 ml (67 mg fipronil + 60.3 mg (S)-methoprene) per dog weighing over 2 and up to 10 kg corresponding 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.

Dogs >10-20 kg (dogs weighing over 10 kg and up to 20 kg)

One pipette of 1.34 ml (134 mg fipronil + 120.6 mg (S)-methoprene) per dog weighing over 10 kg and up to 20 kg corresponding 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.

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

One pipette of 2.68 ml (268 mg fipronil + 241.2 mg (S)-methoprene) per dog weighing over 20 kg and up to 40 kg corresponding 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.

Dogs >40 kg (dogs weighing over 40 kg)

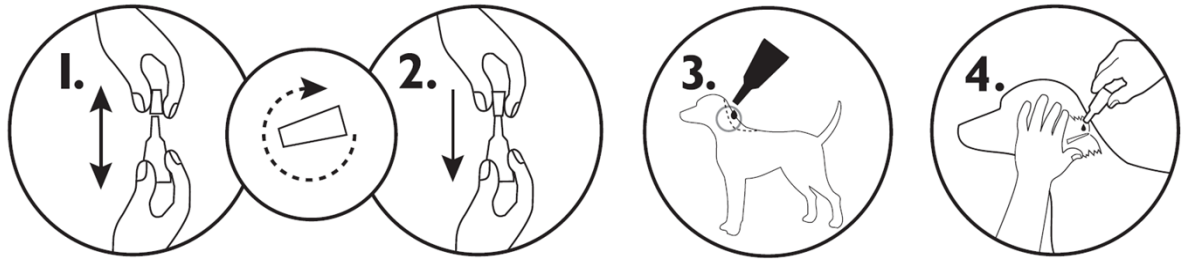
One pipette of 4.02 ml (402 mg fipronil + 361.8 mg (S)-methoprene) per dog weighing over 40 kg corresponding to a minimum recommended dose of 6.7 mg/kg for fipronil and 6 mg/kg for (S)-methoprene, by topical application to the skin.

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

9. ADVICE ON CORRECT ADMINISTRATION

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. Apply to the skin at the base of the neck in front of the shoulder blades.
4. Part the coat 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.



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

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 30 °C.

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 label after {EXP}. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

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 weeks 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 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.

Do not overdose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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, 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 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.

Other precautions:

Dogs should not be allowed to swim in watercourses for 2 days after application.

Pregnancy and lactation:

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 (symptoms, emergency procedures, antidotes):

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 4.6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

Incompatibilities:

None known.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Fipronil and S-methoprene may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

15. OTHER INFORMATION

White polypropylene single-dose pipette packaged in aluminium foil sachets.
Cardboard box containing 1, 3 or 6 pipettes.
Not all pack sizes may be marketed.

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

Approved 12 February 2021

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date.