PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Krka 402 mg/ 361.8 mg spot-on solution for extra large dogs
Fipronil, S-Methoprene

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

WHAT'S IN THIS PRODUCT?
Each pipette contains 402 mg Fipronil, 361.8 mg S-methoprene (active ingredients), 0.80 mg Butylhydroxyanisole (E320) and 0.40 mg Butylhydroxytoluene (E321).

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)

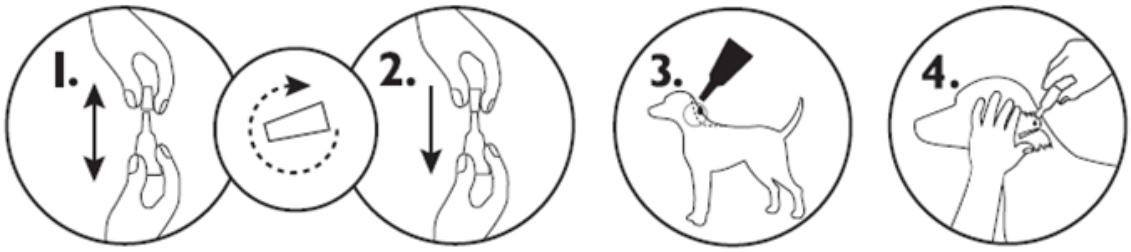
- Kills fleas, ticks and lice
- Protects for up to 8 weeks against fleas

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*).

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, tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette, 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. 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.

IS THIS PRODUCT SUITABLE FOR MY DOG?
Only use Krka 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 insecticides or alcohol should avoid contact with the 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, and dispose of used pipettes immediately.
As fipronil and S-methoprene may adversely affect aquatic organisms, dogs should not be allowed to swim in watercourses for 2 days after treatment.

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

HOW SHOULD I 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.
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 01656/5021

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{ BAG }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Krka 402 mg/ 361.8 mg spot-on solution for extra large dogs
Fipronil, S-Methoprene

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

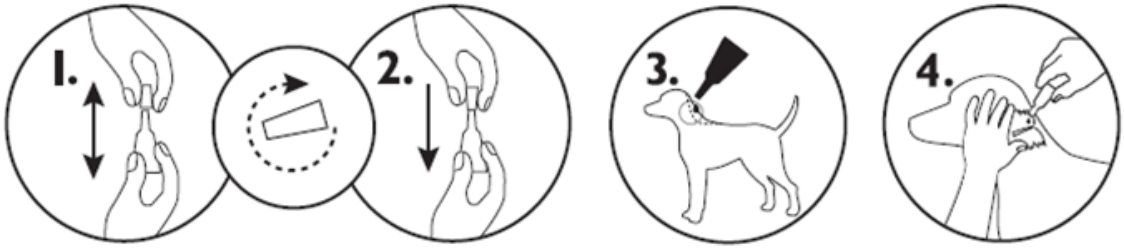
3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 x 4.02 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.
Extra large Dogs (40 – 60 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

Krka 402 mg/ 361.8 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:

Krka 67 mg/60.3 mg spot-on solution for small dogs
Krka 134 mg/120.6 mg spot-on solution for medium dogs
Krka 268 mg/241.2 mg spot-on solution for large dogs
Krka 402 mg/361.8 mg spot-on solution for extra large dogs
Fipronil, S-Methoprene

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

Krka 67 mg/60.3 mg spot-on solution for small dogs

Krka 134 mg/120.6 mg spot-on solution for medium dogs

Krka 268 mg/241.2 mg spot-on solution for large dogs

Krka 402 mg/361.8 mg spot-on solution for extra large dogs

Fipronil, S-Methoprene

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

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.
Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.
Do not use if your dog has a hypersensitivity to the active substances or to any of the excipients.
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 serious effects or other effects not mentioned here, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

Route of administration and dosage:
External use only.

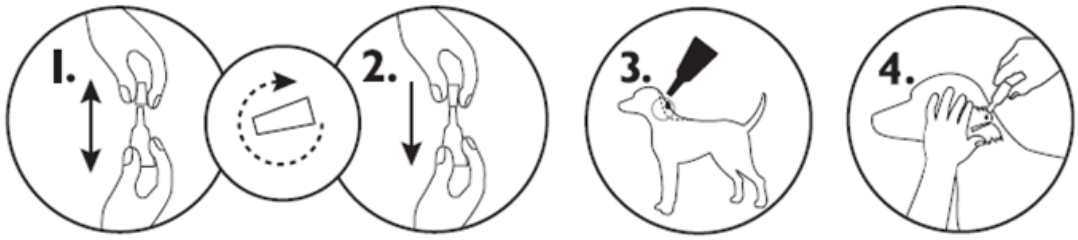
Administer by topical application to the skin according to the bodyweight as follows:

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, tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette, 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.



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 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.

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 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 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.

Dogs should not be allowed to swim in watercourses for 2 days after application.
Animals should be weighed accurately prior to treatment.

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 insecticides or alcohol should avoid contact with the 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 with 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, and dispose of used pipettes immediately.

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 (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.

Other precautions:

The alcohol carrier may have adverse effects on painted, varnished or other household surfaces or furnishings.

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. 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.

15. OTHER INFORMATION

Cardboard box containing 1, 3 or 6 pipettes.
Not all pack sizes may be marketed.

AVM-GSL
For animal treatment only.

Local representative:
KRKA UK Ltd, United Kingdom, Tel: 02071 646 156, Email: info.uk@krka.biz

Approved 12 April 2024