

*[Version 9,03/2022] corr. 11/2022*

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FYPERIX combo 67 mg/ 60.3 mg spot-on solution for small dogs (ES)

FYPRYST combo 67 mg/ 60.3 mg spot-on solution for small dogs (CZ, SK)

FIPROTEC combo 67 mg/ 60.3 mg spot-on solution for small dogs (FR, IT)

Poows Anti Vlo & Teek Combo 67 mg/60.3 mg spot-on solution for small dogs (NL)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.67 ml pipette contains:

### Active substance:

Fipronil	67 mg
S-Methoprene	60.3 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylhydroxyanisole (E320)	0.134 mg
Butylhydroxytoluene (E321)	0.067 mg
Povidone (K25)	
Polysorbate 80	
Ethanol 96 per cent	
Diethylene glycol monoethyl ether	

Clear yellow solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs 2-10 kg

### 3.2 Indications for use for each target species

For the treatment of dogs, dosage defined by bodyweight grouping (refer to section 3.9):

- 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 veterinary medicinal product has persistent acaricidal efficacy for up to 4 weeks against ticks.
- Treatment of infestations with biting lice (*Trichodectes canis*).

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD), where this has been previously diagnosed by a veterinary surgeon.

### 3.3 Contraindications

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

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

**Do not use in rabbits due to a risk of adverse reactions or even death.**

This veterinary medicinal product is specifically developed for dogs. Do not use in cats and ferrets, as this could lead to overdosing.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

### 3.4 Special warnings

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, as no study has been performed to investigate how this affects the efficacy of the veterinary medicinal 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 veterinary medicinal product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6-week long study. For the treatment and control of flea allergy dermatitis it is recommended that allergic patients and all other animals in the household should be treated on a regular basis.

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.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

The attachment of single ticks after treatment cannot be ruled out. Therefore, the transmission of infectious disease cannot be completely excluded if conditions are unfavourable.

For external use only. Do not administer orally.

Avoid contact with the eyes of the animal. If the veterinary medicinal product is in contact with eyes, rinse immediately with plenty of water.

Do not apply the veterinary medicinal product on wounds or skin lesions.

It is important to make sure that the veterinary medicinal product is applied directly onto an area of dry skin where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

Wait for the application site to dry before allowing the treated dog to come into contact with valuable fabrics or furnishings.

#### 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 known hypersensitivity to fipronil or s-methoprene and/or any of the ingredients 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.

Wash hands after use.

In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

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 the original packaging until ready to use, and dispose of used pipettes immediately.

### Special precautions for the protection of the environment:

Dogs should not be allowed to swim in watercourses for 2 days after application (see section 5.5).

### **3.6 Adverse events**

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site hair loss <sup>1</sup> , Application site itching <sup>1</sup> , Application site reddening <sup>1</sup> , Application site skin discolouration <sup>1</sup>  Itching, General hair loss  Hypersalivation <sup>2</sup> , Vomiting  Neurological signs <sup>3</sup> , Hyperaesthesia <sup>3</sup>  Respiratory signs  Depression <sup>3</sup>
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<sup>1</sup> Transient

<sup>2</sup> May be observed briefly in the case of licking the administration site, also (mainly due to the nature of the carrier)

<sup>3</sup> Reversible

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### **3.7 Use during pregnancy, lactation or lay**

#### Pregnancy and lactation:

Can be used during pregnancy and lactation.

### **3.8 Interaction with other medicinal products and other forms of interaction**

None known.

### **3.9 Administration routes and dosage**

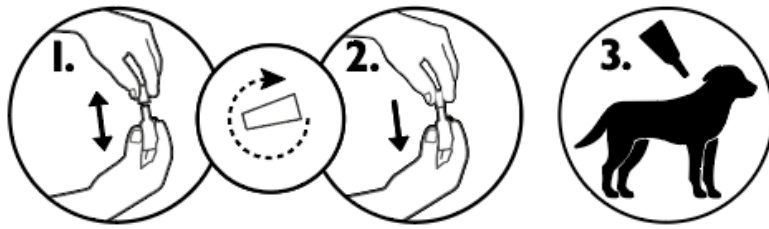
External use only, spot-on use.

Administer by topical application to the skin; one pipette of 0.67 ml (67 mg fipronil + 60.3 mg (S)-methoprene) per dog weighing over 2 and up to 10 kg. 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.

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

#### 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. 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.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events 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 events (see section 3.6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Not applicable.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QP53AX65

### 4.2 Pharmacodynamics

**Fipronil** is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by interacting with ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarines. Fipronil kills fleas within 24 hours and ticks (*Dermacentor reticulatus*, *Dermacentor variabilis*, *Rhipicephalus sanguineus*, *Ixodes scapularis*, *Ixodes ricinus*, *Haemaphysalis longicornis*, *Haemaphysalis flava*, *Haemaphysalis campanulata*) and lice within 48 hours post-exposure.

**(S)-Methoprene** is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues that inhibit the development of immature stages of insects. This compound mimics the action of juvenile hormone and causes impaired development and death of the developing stages of fleas. The on-animal ovicidal activity of (S)-methoprene results from either direct penetration of the eggshell of newly laid eggs or from absorption through the cuticle of the adult fleas. (S)-methoprene is also effective in preventing flea larvae and pupae from developing, which prevents contamination of the environment of the treated animals with the immature stages of fleas.

### 4.3 Pharmacokinetics

Studies of metabolism of fipronil have demonstrated that the major metabolite is the sulfone derivative of fipronil.

(S)-methoprene is extensively degraded into carbon dioxide and acetate that are subsequently incorporated into endogenous materials.

The pharmacokinetic profiles after topical application of fipronil and (S)-methoprene in combination were studied in dogs in comparison to intravenous dosing of fipronil or (S)-methoprene alone. This established absorption and other pharmacokinetic parameters. The topical application resulted in low systemic absorption of fipronil (11%) with a mean maximum concentration ( $C_{max}$ ) of approximately 35 ng/ml fipronil and 55 ng/ml of fipronil sulfone in plasma.

Peak fipronil plasma concentrations are slowly attained (mean  $t_{max}$  approximately 101 h), and decline slowly (mean terminal half-life approximately 154 h, highest values are observed for males).

Fipronil is extensively metabolised to fipronil sulfone after topical administration.

Plasma concentrations of (S)-methoprene were below the limit of quantitation (20 ng/ml) in dogs after topical application.

Both (S)-methoprene and fipronil, together with its major metabolite, are well-distributed in the haircoat of a dog within one day after application. The concentrations of fipronil, fipronil sulfone and (S)-methoprene in the hair coat decrease with time and are detectable for at least 60 days after dosing. Parasites are killed through contact rather than systemic exposure.

No pharmacological interaction between fipronil and (S)-methoprene was noted.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

None known.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

### **5.3 Special precautions for storage**

Store in the original package in order to protect from light and moisture.

This veterinary medicinal product does not require any special temperature storage conditions.

### **5.4 Nature and composition of immediate packaging**

White polypropylene unit-dose pipette with polyethylene or polyoxymethylene closure with spike packaged into laminated triplex bag composed of polyester, aluminium and polyethylene.

#### Pack sizes:

Cardboard box containing 1, 3, 6, 10, 30 pipettes.

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater or household waste.

The 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 national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

KRKA, d.d., Novo mesto

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation:

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product not subject to prescription (CZ, FR, IT, NL, SK, ES).

Veterinary medicinal product subject to prescription except for some pack sizes (CZ).

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{NATURE/TYPE}

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FYPERIX combo 67 mg/ 60.3 mg spot-on solution (ES)  
FYPRYST combo 67 mg/ 60.3 mg spot-on solution (CZ, SK)  
FIPROTEC combo 67 mg/ 60.3 mg spot-on solution (FR, IT)  
Poows Anti Vlo & Teek Combo 67 mg/60.3 mg spot-on solution (NL)

### 2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.67 ml pipette contains:

fipronil	67 mg
s-methoprene	60.3 mg

### 3. PACKAGE SIZE

1 x 0.67 ml  
3 x 0.67 ml  
6 x 0.67 ml  
10 x 0.67 ml  
30 x 0.67 ml

### 4. TARGET SPECIES

Dogs  
2-10 kg



### 5. INDICATIONS

For use against flea infestations, alone or in association with ticks and/or biting lice.

*For products not subject to veterinary prescription:*



*Ixodida*



*Ctenocephalides felis*

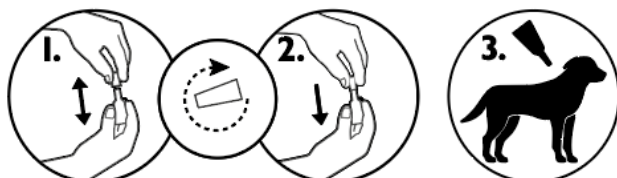


*Trichodectes canis*

## 6. ROUTES OF ADMINISTRATION

External use only.

Spot-on use.



## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp.

## 9. SPECIAL STORAGE PRECAUTIONS

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.

## 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

Marketing authorisation holder:  
KRKA, d.d., Novo mesto

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**BAG**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FYPERIX combo spot-on solution (ES)  
FYPRYST combo spot-on solution (CZ, SK)  
FIPROTEC combo spot-on solution (FR, IT)  
Poows Anti Vlo & Teek Combo spot-on solution (NL)

2-10 kg



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

fipronil /s-methoprene  
67 mg/60.3 mg

**3. BATCH NUMBER**

Lot

**4. EXPIRY DATE**

Exp.

Marketing authorisation holder:  
KRKA, d.d., Novo mesto

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**PIPETTE**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FYPERIX combo (ES)  
FYPRYST combo (CZ, SK)  
FIPROTEC combo (FR, IT)  
Poows Anti Vlo & Teek Combo (NL)



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

2-10 kg

**3. BATCH NUMBER**

Lot

**4. EXPIRY DATE**

Exp.

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

FYPERIX combo 67 mg/ 60.3 mg spot-on solution for small dogs  
FYPERIX combo 134 mg/ 120.6 mg spot-on solution for medium dogs  
FYPERIX combo 268 mg/ 241.2 mg spot-on solution for large dogs  
FYPERIX combo 402 mg/ 361.8 mg spot-on solution for extra large dogs  
(ES)

FYPRYST combo 67 mg/ 60.3 mg spot-on solution for small dogs  
FYPRYST combo 134 mg/ 120.6 mg spot-on solution for medium dogs  
FYPRYST combo 268 mg/ 241.2 mg spot-on solution for large dogs  
FYPRYST combo 402 mg/ 361.8 mg spot-on solution for extra large dogs  
(CZ, SK)

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  
(FR, IT)

Poows Anti Vlo & Teek Combo 67 mg/60.3 mg spot-on solution for small dogs  
Poows Anti Vlo & Teek Combo 134 mg/ 120.6 mg spot-on solution for medium dogs  
Poows Anti Vlo & Teek Combo 268 mg/ 241.2 mg spot-on solution for large dogs  
Poows Anti Vlo & Teek Combo 402 mg/ 361.8 mg spot-on solution for extra large dogs  
(NL)

### 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 2-10 kg  
Dogs 10-20 kg  
Dogs 20-40 kg  
Dogs > 40 kg

**4. Indications for use**

For the treatment of dogs, dosage defined by bodyweight grouping (refer to section 3.9):

- 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 veterinary medicinal product has persistent acaricidal efficacy for up to 4 weeks against ticks.
- Treatment of infestations with biting lice (*Trichodectes canis*).

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD), where this has been previously diagnosed by a veterinary surgeon.

**5. Contraindications**

In the absence of supporting data, this veterinary medicinal product should not be used in puppies less than 8 weeks old.

Always establish the appropriate dosage according to bodyweight before using this veterinary medicinal product. In the absence of supporting data, the product for dogs of 2-10 kg bodyweight should not be used in dogs weighing less than 2 kg.

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

**Do not use in rabbits due to a risk of adverse reactions or even death.**

This veterinary medicinal product is specifically developed for dogs. Do not use in cats and ferrets, as this could lead to overdosing.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

## **6. Special warnings**

### Special warnings:

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, as no study has been performed to investigate how this affects the efficacy of the veterinary medicinal 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 veterinary medicinal product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6-week long study. For the treatment and control of flea allergy dermatitis it is recommended that allergic patients and all other animals in the household should be treated on a regular basis. 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:

The attachment of single ticks after treatment cannot be ruled out. Therefore, the transmission of infectious disease cannot be completely excluded if conditions are unfavourable.

For external use only. Do not administer orally.

Avoid contact with the eyes of the animal. If the veterinary medicinal product is in contact with eyes, rinse immediately with plenty of water.

Do not apply the veterinary medicinal product on wounds or skin lesions.

It is important to make sure that the veterinary medicinal product is applied directly onto an area of dry skin where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

Wait for the application site to dry before allowing the treated dog to come into contact with valuable fabrics or furnishings.

### 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 known hypersensitivity to fipronil or s-methoprene and/or any of the ingredients 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.

Wash hands after use.

In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

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 the original packaging until ready to use, and dispose of used pipettes immediately.

### Special precautions for the protection of the environment:

Dogs should not be allowed to swim in watercourses for 2 days after application (see section 12).

### Pregnancy and lactation:

Can be used during pregnancy and lactation.

### Overdose:

No adverse events 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 events (see section “Adverse events”) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

## 7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site hair loss <sup>1</sup> , Application site itching <sup>1</sup> , Application site reddening <sup>1</sup> , Application site skin discolouration <sup>1</sup> Itching, General hair loss Hypersalivation <sup>2</sup> , Vomiting Neurological signs <sup>3</sup> , Hyperaesthesia <sup>3</sup> Respiratory signs Depression <sup>3</sup>
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<sup>1</sup> Transient

<sup>2</sup> May be observed briefly in the case of licking the administration site, also (mainly due to the nature of the carrier)

<sup>3</sup> Reversible

Reporting adverse events is important. It allows continuous safety monitoring of a 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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

External use only, spot-on use.

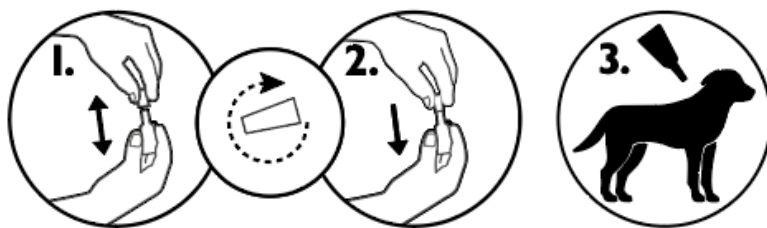
Administer by topical application to the skin according to the bodyweight as follows:

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

#### **10. Withdrawal periods**

Not applicable.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

Store in the original package in order to protect from light and moisture.

This veterinary medicinal product does not require any special temperature storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the labels and 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 or household waste.

The 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.

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 (CZ, FR, IT, NL, SK, ES).  
Veterinary medicinal product subject to prescription except for some pack sizes (CZ).

#### **14. Marketing authorisation numbers and pack sizes**

White polypropylene unit-dose pipette with polyethylene or polyoxymethylene closure with spike packaged into laminated triplex bag composed of polyester, aluminium and polyethylene.

Pack sizes:

Cardboard box containing 1, 3, 6, 10, 30 pipettes.

Not all pack sizes may be marketed.

**15. Date on which the package leaflet was last revised**

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

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

Local representatives and contact details to report suspected adverse reactions:

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

**17. Other information**