[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eliminall 67 mg spot-on solution for dogs (DE, GR, PT)
Exproline vet 67 mg spot-on solution for dogs (FI)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.67 ml pipette contains:

Active substances:
Fipronil 67 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisol (E320)	0.134 mg
Butylhydroxytoluene (E321)	0.067 mg
Polysorbate 80	
Povidone K25	
Dimethyl sulfoxide	

Light yellow to yellow, clear liquid.

3. CLINICAL INFORMATION

3.1 Target species

Dogs (>2 kg ≤ 10 kg)

3.2 Indications for use for each target species

Treatment of flea (*Ctenocephalides* spp.) and tick (*Dermacentor reticulatus*) infestations.
For treatment of *Trichodectes canis* biting lice infestations on dogs. Most lice are killed within 2 days.
Insecticidal efficacy against new infestations with adult fleas persists for up to 8 weeks.
The veterinary medicinal product has a persistent acaricidal efficacy for up to 3 weeks against *Ixodes ricinus* and up to 4 weeks against *Rhipicephalus sanguineus* and *Dermacentor reticulatus*. If ticks of some species (*Ixodes ricinus*, *Rhipicephalus sanguineus*) are present when the veterinary medicinal product is applied, all the ticks may not be killed within the first 48 hours.
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

Do not use in puppies less than 2 months old and/or weighing less than 2 kg in the absence of available data.
Do not use in sick (e.g. systemic diseases, fever…) or convalescent animals.
Do not use in rabbits, as adverse reactions and even death could occur.
This veterinary medicinal product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

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

3.4 Special warnings

Bathing/immersion in water within two days after application of the veterinary medicinal product should be avoided. After weekly immersions in water for one minute the period of persistent insecticidal efficacy against fleas was 7 weeks.

The veterinary medicinal product does not prevent ticks from attaching to the animals. If the animal has been treated prior to exposure to the ticks, the ticks will be killed in the first 24-48 hours after attachment. This will usually be prior to engorgement, minimising but not excluding the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may be removed with a gentle pull.

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.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other dogs in the household are recommended.

For optimal control of flea infestation in multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

It is important to make sure that the veterinary medicinal 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 apply the veterinary medicinal product on wounds or damaged skin.

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

This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the veterinary medicinal product and the mouth or eyes should be avoided.
In the case of accidental eye contact immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
Do not smoke, drink or eat during application.
Avoid contents coming into contact with the fingers. If this occurs, wash off immediately with soap and water.
Wash hands after use.
People with a known hypersensitivity to fipronil or dimethyl sulfoxide or other excipients should avoid contact with the veterinary medicinal product.
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 should not be allowed to sleep with owners, especially children.
Keep pipettes in the original packaging and dispose of used pipette immediately.

Special precautions for the protection of the environment:

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site alopecia[1], Application site pruritus[1], Application site erythema[1], Application site skin discolouration[1] General itching, Alopecia general Hypersalivation, Vomiting Neurological signs[3], Hyperaesthesia[3] Respiratory signs Depression[3]
Undetermined (cannot be estimated from the available data)	Hypersalivation[2]

[1] Transient.
[2] May be observed for a brief period in the case of licking the administration site.
[3] 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:

Laboratory studies have not produced any evidence of teratogenic or embryotoxic effect. Studies have not been carried out with this veterinary medicinal product in pregnant and lactating bitches. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

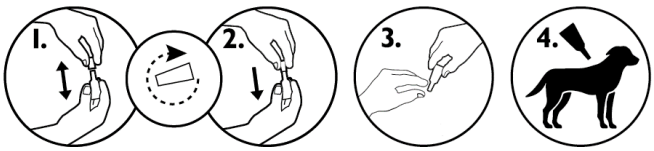
3.9 Administration routes and dosage

Route of administration and dosage:
Spot-on use. External use only.
Administer by topical application to the skin according to the bodyweight as follows:
1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight.

To ensure a correct dosage, body weight should be determined as accurately as possible

Method of administration:
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. Spread the animal hairs in the area between the

shoulder blades to make the skin visible. Put the tip of the pipette onto the skin and press the unit-dose pipette several times to empty its contents directly onto the skin at one or two spots.



It is important to make sure that the veterinary medicinal 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. Temporary changes to the coat (clumped/greasy hair and/or deposits on the hair) may be noted at the application site.

Treatment schedule:
For optimal control of flea and/or tick infestation the treatment schedule can be based on the local epidemiological situation.
In the absence of safety studies, the minimum treatment interval is 4 weeks.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 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 : QP53AX15

4.2 Pharmacodynamics

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by inhibiting the GABA complex, binding to the chloride channel and 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 acarids.
Fipronil exhibits an insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp), ticks (*Rhipicephalus* spp, *Dermacentor* spp, *Ixodes* spp including *Ixodes ricinus*, and lice (*Trichodectes canis*) in the dog. Ticks will usually be killed within 48 h after contact with Fipronil, however if ticks of some species (*Ixodes ricinus, Rhipicephalus sanguineus*) are already present when the veterinary medicinal product is applied, all of the ticks may not be killed within the first 48 hours. Fleas will be killed within 24 hours.

4.3 Pharmacokinetics

Fipronil is mainly metabolised to its sulfone derivative (RM1602), which also possesses insecticidal and acaricidal properties. The concentrations of fipronil on the hair decrease with time.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Store in the original container in order to protect from light and moisture.
The veterinary medicinal product should be maintained at room temperature (above 14°C) for approximately one hour prior to administration.

5.4 Nature and composition of immediate packaging

White polypropylene pipette closed with either a polyethylene or polyoxymethylene cap. Each pipette is packed in a polyethylene terephthalate/aluminium/low density polyethylene triplex bag.

Pack sizes:
Box containing 1, 3, 6, 10, 20 or 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

The veterinary medicinal product should not enter water courses as Fipronil may be dangerous for fish and other aquatic organisms.

Do not contaminate ponds, waterways or ditches with the product or empty container.
Medicines should not be disposed of via wastewater or household waste.
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

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription (GR).
Veterinary medicinal product not subject to prescription (FI, DE, PT).

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eliminall 67 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.67 ml pipette contains:

fipronil 67 mg

3. PACKAGE SIZE

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

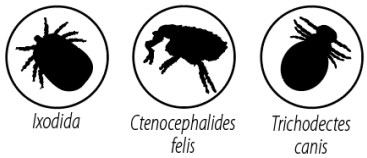
4. TARGET SPECIES

Dogs >2 kg ≤ 10 kg

5. INDICATIONS

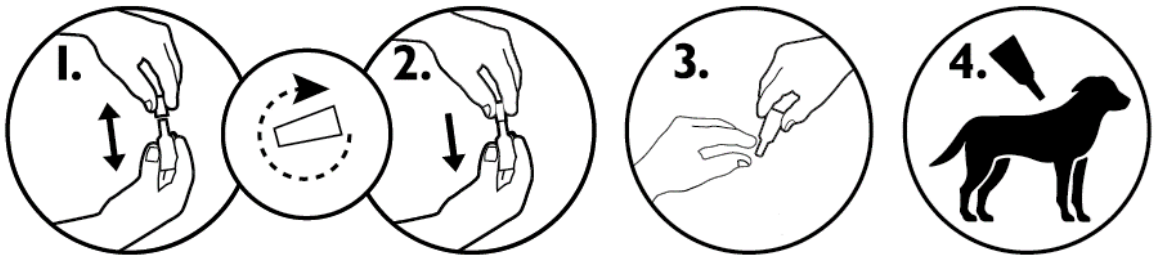
Treatment of fleas, ticks and lice.

For products not subject to veterinary prescription:



6. ROUTES OF ADMINISTRATION

Spot-on use.



7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container in order to protect from light and moisture.
The veterinary medicinal product should be maintained at room temperature (above 14°C) for approximately one hour prior to administration.

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

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

Eliminall

>2 kg ≤ 10 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

fipronil 67 mg

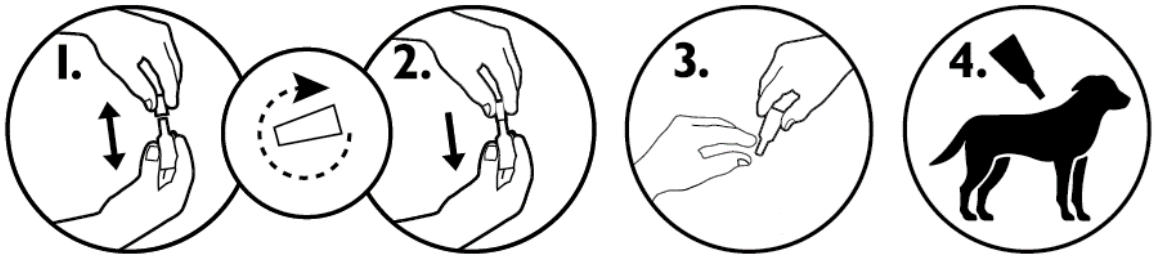
3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.

KRKA



MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eliminall

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

>2 kg ≤ 10 kg

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Eliminall 67 mg spot-on solution for dogs
Eliminall 134 mg spot-on solution for dogs
Eliminall 268 mg spot-on solution for dogs
Eliminall 402 mg spot-on solution for dogs

2. Composition

Each 0.67 ml pipette contains:
Active substance:
Fipronil 67 mg

Excipients:
Butylhydroxyanisole (E320) 0.134 mg
Butylhydroxytoluene (E321) 0.067 mg

Each 1.34 ml pipette contains:
Active substance:
Fipronil 134 mg

Excipients:
Butylhydroxyanisole (E320) 0.27 mg
Butylhydroxytoluene (E321) 0.13 mg

Each 2.68 ml pipette contains:
Active substance:
Fipronil 268 mg

Excipients:
Butylhydroxyanisole (E320) 0.54 mg
Butylhydroxytoluene (E321) 0.27 mg

Each 4.02 ml pipette contains:
Active substance:
Fipronil 402 mg

Excipients:
Butylhydroxyanisole (E320) 0.80 mg
Butylhydroxytoluene (E321) 0.40 mg

Light yellow to yellow, clear liquid.

3. Target species

Dogs >2 kg ≤ 10 kg
Dogs >10 kg ≤ 20 kg
Dogs >20 kg ≤ 40 kg
Dogs > 40 kg

4. Indications for use

Treatment of flea (*Ctenocephalides* spp.) and tick (*Dermacentor reticulatus*) infestations.
For treatment of *Trichodectes canis* biting lice infestations on dogs. Most lice are killed within 2 days.
Insecticidal efficacy against new infestations with adult fleas persists for up to 8 weeks.
The veterinary medicinal product has a persistent acaricidal efficacy for up to 3 weeks against *Ixodes ricinus* and up to 4 weeks against *Rhipicephalus sanguineus* and *Dermacentor reticulatus*. If ticks of some species (*Ixodes ricinus*, *Rhipicephalus sanguineus*) are present when the veterinary medicinal product is applied, all the ticks may not be killed within the first 48 hours.
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

Do not use in puppies less than 2 months old and/or weighing less than 2 kg in the absence of available data.
Do not use in sick (e.g. systemic diseases, fever…) or convalescent animals.
Do not use in rabbits, as adverse reactions and even death could occur.
This veterinary medicinal product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
Bathing/immersion in water within two days after application of the veterinary medicinal product should be avoided. After weekly immersions in water for one minute the period of persistent insecticidal efficacy against fleas was 7 weeks.
The veterinary medicinal product does not prevent ticks from attaching to the animals. If the animal has been treated prior to exposure to the ticks, the ticks will be killed in the first 24-48 hours after attachment. This will usually be prior to engorgement, minimising but not excluding the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may be removed with a gentle pull.
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.
When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other dogs in the household are recommended.
For optimal control of flea infestation in multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

Special precautions for safe use in the target species:

Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

It is important to make sure that the veterinary medicinal 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 apply the veterinary medicinal product on wounds or damaged skin.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the veterinary medicinal product and the mouth or eyes should be avoided.
In the case of accidental eye contact immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
Do not smoke, drink or eat during application.
Avoid contents coming into contact with the fingers. If this occurs, wash off immediately with soap and water.
Wash hands after use.
People with a known hypersensitivity to fipronil or dimethyl sulfoxide or other excipients should avoid contact with the veterinary medicinal product.
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 should not be allowed to sleep with owners, especially children.
Keep pipettes in the original packaging and dispose of used pipette immediately.

Special precautions for the protection of the environment:
Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

Pregnancy and lactation:
Laboratory studies have not produced any evidence of teratogenic or embryotoxic effect. Studies have not been carried out with this veterinary medicinal product in pregnant and lactating bitches. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
None known.

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

Major incompatibilities:
None known.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site alopecia (hair loss)[1], Application site pruritus (itching)[1], Application site erythema (reddening)[1], Application site skin discolouration[1] General itching, Alopecia general (General hair loss) Hypersalivation, Vomiting Neurological signs[3], Hyperaesthesia[3] Respiratory signs Depression[3]

Undetermined (cannot be estimated from the available data)	Hypersalivation[2]

[1] Transient.
[2] May be observed for a brief period in the case of licking the administration site.
[3] 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

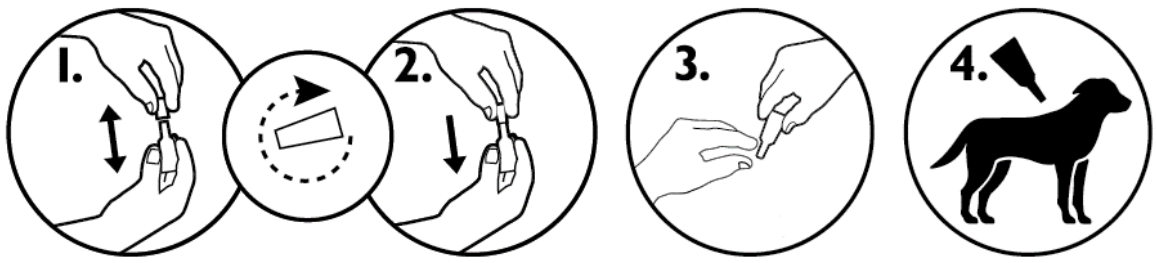
Route of administration and dosage:
Spot-on use. External use only.

To ensure a correct dosage, body weight should be determined as accurately as possible

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

Dogs	**Number of pipettes**	**Pippete volume**	**Potency**
over 2 kg and up to 10 kg	1 pipette	0.67 ml	67 mg
over 10 kg and up to 20 kg	1 pipette	1.34 ml	134 mg
over 20 kg and up to 40 kg	1 pipette	2.68 ml	268 mg
40 kg and up to 60 kg	1 pipette	4.02 ml	402 mg
over 60 kg	1 pipette + appropriate smaller pipette	4.02 ml + appropriate combination	402 mg + appropriate combination

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. Spread the animal hairs in the area between the shoulder blades to make the skin visible.
4. Put the tip of the pipette onto the skin and press the unit-dose pipette several times to empty its contents directly onto the skin at one or two spots.



9. Advice on correct administration

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.
Temporary changes to the coat (clumped/greasy hair and/or deposits on the hair) may be noted at the application site.
For optimal control of flea and/or tick infestation the treatment schedule can be based on the local epidemiological situation.
In the absence of safety studies, the minimum treatment interval is 4 weeks.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original container in order to protect from light and moisture.
The veterinary medicinal product should be maintained at room temperature (above 14°C) for approximately one hour prior to administration.

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

This veterinary medicinal product should not enter water courses as Fipronil may be dangerous for fish and other aquatic organisms.
Do not contaminate ponds, waterways or ditches with the product or empty container.

Medicines should not be disposed of via wastewater or household waste.
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 subject to prescription (GR).
Veterinary medicinal product not subject to prescription (FI, DE, PT).

14. Marketing authorisation numbers and pack sizes

White polypropylene pipette closed with either a polyethylene or polyoxymethylene cap. Each pipette is packed in a polyethylene terephthalate/aluminium/low density polyethylene triplex bag.

Pack sizes:

Box containing 1, 3, 6, 10, 20 or 30 pipettes.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (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.