[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eliminall 2.5 mg/ml cutaneous spray, solution for cats and dogs (DE, PT)
Exproline vet 2.5 mg/ml cutaneous spray, solution for cats and dogs (FI)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substances:
Fipronil 2.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Copovidone	
Isopropyl alcohol	
Purified water	

Clear, colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cats and dogs.

3.2 Indications for use for each target species

Treatment of flea (*Ctenocephalides* spp.) and tick (*Ixodes ricinus*, *Rhipicephalus sanguineus*) infestations in dogs and cats.
Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).
The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).
Insecticidal efficacy against new infestations with adult fleas persists for up to 2 months in cats and up to 3 months in dogs, depending on environmental challenge.
The veterinary medicinal product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.

3.3 Contraindications

Do not use on sick (systemic diseases, fever) or convalescent animals.
Do not use in rabbits, as adverse reactions and even death could occur.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Do not exceed the recommended dosage.
Allow treated animals to dry in a well ventilated room (see also section 3.5).

Do not confine animals in an enclosed space or pet carrier until the coat is totally dry.
In the absence of specific tolerance and efficacy data, the veterinary medicinal product is not recommended for the treatment of species other than cats and dogs.
For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.
When used as part of a strategy for the treatment of flea allergy dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended.
Treatment of bedding, carpets and soft furnishings with a suitable insecticide will aid reduction in environmental challenge and maximise the duration of protection against re-infestation provided by the veterinary medicinal product.
The veterinary medicinal product is not suitable for direct treatment of the environment.
For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the veterinary medicinal product. Bathing or shampooing up to four times in two months has been shown to have no significant effect on the residual efficacy of the veterinary medicinal product. Monthly treatment is recommended when more frequent shampooing is carried out.

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. If eye irritation persists, seek veterinary medical advice.
Do not spray directly onto areas of injured skin.
It is important to make sure that animals do not lick each other following treatment.
There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.
Keep treated animals away from fires or other sources of heat, and surfaces likely to be affected by the alcohol spray, for at least 30 minutes following spraying and until the fur is totally dry. Do not spray on a naked flame or any incandescent material.
Puppies and kittens from 2 days of age may be safely treated.
For external use only.

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 of the veterinary medicinal product with mouth and eyes should be avoided. After accidental ocular exposure the eye should be rinsed carefully with plain water.
People with known hypersensitivity to the active substance or alcohol or with asthma should avoid contact with the veterinary medicinal product. Do not use veterinary medicinal product if you have previously experienced a reaction to it.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

Treated animals should not be handled until the fur is dry, and children should not be allowed to play with treated animals until the fur 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.

Spray animals in the open air or a well ventilated room.
Do not breathe spray. Do not smoke, drink or eat during application.
Personal protective equipment consisting of PVC or nitrile gloves should be worn when handling the veterinary medicinal product. It is recommended to wear a waterproof apron for the protection of clothing. If clothing becomes heavily wetted with the veterinary medicinal product, it should be removed and washed before re-use

Dispose of gloves after use and then wash hands with soap and water.

Wash splashes from skin with soap and water immediately. If irritation occurs, seek medical adviceand show the package leaflet or the label to the physician.

Treatment of multiple animals: Good ventilation is particularly important where several animals are to be treated. Treat multiple animals outside, or reduce the build up of vapour by removing the animals from the treatment room while the alcohol is evaporating and ensure that the treatment room is well ventilated between individual treatments. In addition, ensure that the drying room is well ventilated and avoid housing several recently treated animals within the same air space.

Special precautions for the protection of the environment:

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

3.6 Adverse events

Dogs, cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Erythema[1], Pruritus[1], Alopecia[1] Hypersalivation, Vomiting Respiratory signs Neurological signs (hyperaesthesia, depression)[3]
Undetermined frequency (cannot be estimated from the available data)	Hypersalivation[2]

[1]Transient, cutaneous reaction.
[2]brief period, if licking occurs (due mainly to the nature of the carrier).
[3]Reversible. Other nervous signs possible.
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 in rats and rabbits have not produced any evidence of teratogenic effects.
The formulation is very well tolerated by puppies following treatment of the lactating bitch.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in queens.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Route of administration: mechanical pump spray for cutaneous use; with the pump delivering 0.5 ml (100 ml bottle) or 1.5 ml (250 ml bottle) or 3 ml (500 ml bottle) spray per pump.

Posology: In order to dampen the coat down to the skin, depending on the length of hair, apply 3 to 6 ml per kg bodyweight, (7.5 to 15 mg of active ingredient per kg bodyweight) i.e. 6 to 12 pump

applications per kg bodyweight of the 100 ml presentation, or 2 to 4 pump applications of the 250 ml, or 1 to 2 pump application(s) of the 500 ml presentation.

The 100 ml pack contains approximately 8 treatments for a short haired medium sized cat (4 kg). The 250 ml pack contains approximately 4 treatments for a short haired medium sized dog (20 kg). The 500 ml pack contains approximately 4 treatments for a short haired large sized dog (40 kg).

Method of administration:
Adjust the pump nozzle to spray setting.
Spray the entire body of the animal, and apply from a distance of approximately 10-20 cm.
Apply against the lay of the hair and make sure that the entire coat of the animal is dampened. Ruffle the coat, especially in long haired animals, so that the veterinary medicinal product penetrates down to the skin.
For treatment of the head region, and when treating young or nervous pets, application may be carried out by spraying onto a gloved hand and rubbing the veterinary medicinal product into the coat. Allow to dry naturally. Do not towel dry.

Properties: The formulation contains a coating agent. Therefore, spraying builds up a film and makes the fur glossy.

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

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

The risk of experiencing adverse effects (see section 3.6) may increase when overdosing, so animals should always be treated with the correct dose according to bodyweight.
Start an appropriate symptomatic treatment in case of overdosing.

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 exhibits insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp), ticks (*Rhipicephalus* spp., *Ixodes* spp.) and lice (*Trichodectes* spp. and *Felicola* spp.) in the dog and cat.

Fipronil is a member of the phenylpyrazole family of broad spectrum, non-systemic, insecticides/acaricides, which acts by blocking the GABA receptor to kill the target parasite on contact. The veterinary medicinal product may aid in the control of a number of ectoparasite species in

dogs and cats. The veterinary medicinal product is active against *Ixodes* spp. including *Ixodes ricinus*, important as the vector of Lyme disease. Treatment with the veterinary medicinal product has been shown to result in a significant reduction in the incidence of flea allergy dermatitis in both dogs and cats.

4.3 Pharmacokinetics

Absorption
The amount of fipronil absorbed by the skin in the dog, after application of the spray to the coat and skin is extremely slight to negligible.

Distribution
The persistence of fipronil on the hair is very long (on average 52.5 ± 11.5 days), given that the limit of quantification of the assay method is 0.25 µg/g.

Biotransformation
In all species fipronil is mainly metabolised to its sulphone derivative (RM1602), which also possesses insecticidal and acaricidal properties.
The RM1602 detected on the hair after spray application in dogs may be explained by its presence in the original raw material.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:3 years
Shelf-life after first opening the immediate packaging: 1 year

5.3 Special precautions for storage

Store below 25°C.
Highly flammable.
Protect from direct sunlight.

5.4 Nature and composition of immediate packaging

Cardboard carton containing an opaque, white 100 ml high density polyethylene bottle fitted with a low density polyethylene/polypropylene pump sprayer capable of delivering 0.5 ml per spray.
Opaque, white 250 ml high density polyethylene bottle fitted with a low density polyethylene/polypropylene pump sprayer capable of delivering 1.5 ml per spray.
Opaque, white 500 ml high density polyethylene bottle fitted with a low density polyethylene/ polypropylene pump sprayer capable of delivering 3.0 ml per spray.

<u>Pack sizes:</u>
100 ml
250 ml
500 ml

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 may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

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: {DD/MM/YYYY}

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

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 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eliminall 2.5 mg/ml cutaneous spray, solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Fipronil 2.5 mg

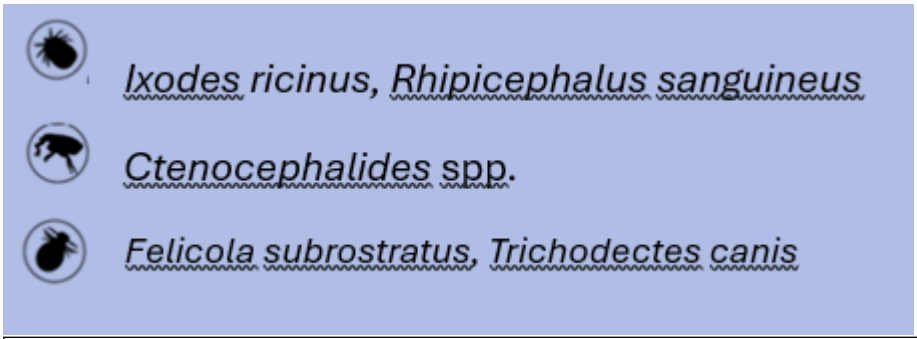
3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Cats and dogs

5. INDICATIONS



6. ROUTES OF ADMINISTRATION

Cutaneous use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 1 year.

9. SPECIAL STORAGE PRECAUTIONS

Highly flammable.
Store below 25 °C.
Protect from direct sunlight.

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 {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 250/500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eliminall 2.5 mg/ml cutaneous spray, solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Fipronil 2.5 mg

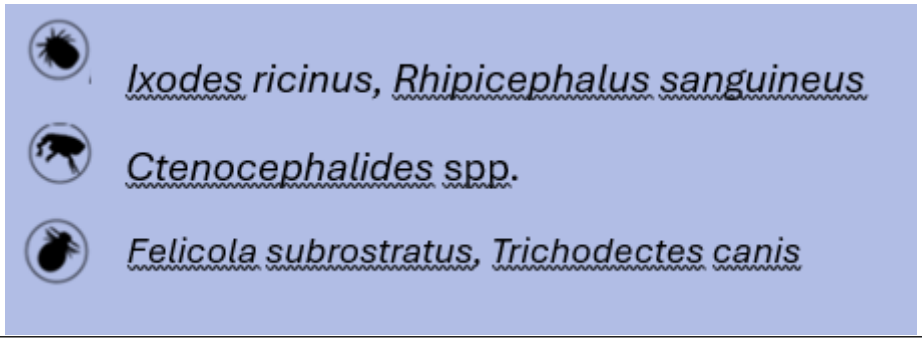
3. PACKAGE SIZE

250 ml
500 ml

4. TARGET SPECIES

Cats and dogs

5. INDICATIONS



6. ROUTES OF ADMINISTRATION

Cutaneous use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 1 year.
Once opened use by……

9. SPECIAL STORAGE PRECAUTIONS

Highly flammable.
Store below 25 °C.
Protect from direct sunlight.

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 {number}

Lot and Exp. are printed on the bottom of the container.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{LABEL 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eliminall 2.5 mg/ml cutaneous spray, solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Fipronil 2.5 mg

3. TARGET SPECIES

Cats and dogs

4. ROUTES OF ADMINISTRATION

Cutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp.{mm/yyyy}
Once opened use within 1 year.
Once opened use by……

7. SPECIAL STORAGE PRECAUTIONS

Highly flammable.
Store below 25 °C.
Protect from direct sunlight.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

9. BATCH NUMBER

Lot {number}

Lot and Exp. are printed on the bottom of the container.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Eliminall 2.5 mg/ml cutaneous spray, solution for cats and dogs

2. Composition

Each ml contains

Active substances:
Fipronil 2.5 mg

Clear, colourless liquid.

3. Target species

Cats and dogs.

4. Indications for use

Treatment of flea (*Ctenocephalides* spp.) and tick (*Ixodes ricinus*, *Rhipicephalus sanguineus*) infestations in dogs and cats.
Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).
The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).
Insecticidal efficacy against new infestations with adult fleas persists for up to 2 months in cats and up to 3 months in dogs, depending on environmental challenge.
The veterinary medicinal product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.

5. Contraindications

Do not use on sick (systemic diseases, fever) or convalescent animals.
Do not use in rabbits, as adverse reactions and even death could occur.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
Do not exceed the recommended dosage.
Allow treated animals to dry in a well ventilated room (see also section “Special precautions to be taken by the person administering the veterinary medicinal product to animals”).
Do not confine animals in an enclosed space or pet carrier until the coat is totally dry.

In the absence of specific tolerance and efficacy data, the veterinary medicinal product is not recommended for the treatment of species other than cats and dogs.
For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.
When used as part of a strategy for the treatment of flea allergy dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended.
Treatment of bedding, carpets and soft furnishings with a suitable insecticide will aid reduction in environmental challenge and maximise the duration of protection against re-infestation provided by the veterinary medicinal product.
The veterinary medicinal product is not suitable for direct treatment of the environment.
For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the veterinary medicinal product. Bathing or shampooing up to four times in two months has been shown to have no significant effect on the residual efficacy of the veterinary medicinal product. Monthly treatment is recommended when more frequent shampooing is carried out.

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. If eye irritation persists, seek veterinary medical advice.
Do not spray directly onto areas of injured skin.
It is important to make sure that animals do not lick each other following treatment.
There may be an attachment of single ticks. For this reason, a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.
Keep treated animals away from fires or other sources of heat, and surfaces likely to be affected by the alcohol spray, for at least 30 minutes following spraying and until the fur is totally dry. Do not spray on a naked flame or any incandescent material.
Puppies and kittens from 2 days of age may be safely treated.
For external use only.

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 of the veterinary medicinal product with mouth and eyes should be avoided. After accidental ocular exposure the eye should be rinsed carefully with plain water.
People with known hypersensitivity to the active substance or alcohol or with asthma should avoid contact with the veterinary medicinal product. Do not use veterinary medicinal product if you have previously experienced a reaction to it.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

Treated animals should not be handled until the fur is dry, and children should not be allowed to play with treated animals until the fur 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.

Spray animals in the open air or a well ventilated room.
Do not breathe spray. Do not smoke, drink or eat during application.
Personal protective equipment consisting of PVC or nitrile gloves should be worn when handling the veterinary medicinal product. It is recommended to wear a waterproof apron for the protection of clothing. If clothing becomes heavily wetted with the veterinary medicinal product, it should be removed and washed before re-use

Dispose of gloves after use and then wash hands with soap and water.
Wash splashes from skin with soap and water immediately. If irritation occurs, seek medical advice.
People with known sensitivity or asthma may be particularly sensitive to the veterinary medicinal product. Do not use veterinary medicinal product if you have previously experienced a reaction to it.

Treatment of multiple animals: Good ventilation is particularly important where several animals are to be treated. Treat multiple animals outside, or reduce the build up of vapour by removing the animals from the treatment room while the alcohol is evaporating and ensure that the treatment room is well ventilated between individual treatments. In addition, ensure that the drying room is well ventilated and avoid housing several recently treated animals within the same air space.

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

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.
The formulation is very well tolerated by puppies following treatment of the lactating bitch.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in queens.

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

Overdose:
The risk of experiencing adverse effects (see section "Adverse events") may increase when overdosing, so animals should always be treated with the correct dose according to bodyweight.
Start an appropriate symptomatic treatment in case of overdosing.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dogs, cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Erythema[1], Pruritus[1], Alopecia[1] Hypersalivation, vomiting Respiratory signs Neurological signs (hyperaesthesia, depression)[3]
Undetermined frequency (cannot be estimated from the available data)	Hypersalivation[2]

[1]Transient, cutaneous reaction.
[2]brief period, if licking occurs (due mainly to the nature of the carrier).
[3]Reversible. Other nervous signs possible.

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 its local representative 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: mechanical pump spray for cutaneous use; with the pump delivering 0.5 ml (100 ml bottle) or 1.5 ml (250 ml bottle) or 3 ml (500 ml bottle) spray per pump..

Posology : In order to dampen the coat down to the skin, depending on the length of hair, apply 3 to 6 ml per kg bodyweight, (7.5 to 15 mg of active ingredient per kg bodyweight) i.e. 6 to 12 pump applications per kg bodyweight of the 100 ml presentation, or 2 to 4 pump applications of the 250 ml presentation, or 1 to 2 pump application(s) of the 500 ml presentation.

Method of administration:
Spray the entire body of the animal, and apply from a distance of approximately 10-20 cm.
Apply against the lay of the hair and make sure that the entire coat of the animal is dampened. Ruffle the coat, especially in long haired animals, so that the veterinary medicinal product penetrates down to the skin.
For treatment of the head region, and when treating young or nervous pets, application may be carried out by spraying onto a gloved hand and rubbing the veterinary medicinal product into the coat. Allow to dry naturally. Do not towel dry.

Properties: The formulation contains a coating agent. Therefore, spraying builds up a film and makes the fur glossy.

9. Advice on correct administration

Adjust the pump nozzle to spray setting.

The 100 ml pack contains approximately 8 treatments for a short haired medium sized cat (4 kg). The 250 ml pack contains approximately 4 treatments for a short haired medium sized dog (20 kg). The 500 ml pack contains approximately 4 treatments for a short haired large sized dog (40 kg).

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

For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the veterinary medicinal product. Bathing or shampooing up to four times in two months has been shown to have no significant effect on the residual efficacy of the veterinary medicinal product. Monthly treatment is recommended when more frequent shampooing is carried out.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25 °C.
Highly flammable.
Protect from direct sunlight.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle and carton after Exp. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 1 year

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 may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

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.

14. Marketing authorisation numbers and pack sizes

Cardboard carton containing an opaque, white 100 ml high density polyethylene bottle fitted with a low density polyethylene/polypropylene pump sprayer capable of delivering 0.5 ml per spray.
Opaque, white 250 ml high density polyethylene bottle fitted with a low density polyethylene/ polypropylene pump sprayer capable of delivering 1.5 ml per spray.
Opaque, white 500 ml high density polyethylene bottle fitted with a low density polyethylene/polypropylene pump sprayer capable of delivering 3.0 ml per spray.

Pack sizes:
100 ml
250 ml
500 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/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 events:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia
Tel.: to be included national

Local representatives and contact details to report suspected adverse events:

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

17. Other information