PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 2.5 mg of fipronil

3. PHARMACEUTICAL FORM

cutaneous spray, solution

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cats and dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Cutaneous use

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once broached,/opened, use by…
Shelf-life after first opening the container: 1 year

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.
Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

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

For animal treatment only.

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 01656/4058

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 2.5 mg of fipronil

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cats and dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Cutaneous use

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once broached,/opened, use by…
Shelf-life after first opening the container: 1 year

11. SPECIAL STORAGE CONDITIONS

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

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

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

For animal treatment only.

14. THE WORDS "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 01656/4058

17. MANUFACTURER'S BATCH NUMBER

Lot:

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE/IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 2.5 mg of fipronil

3. PHARMACEUTICAL FORM

cutaneous spray, solution

4. PACKAGE SIZE

250 ml
500 ml

5. TARGET SPECIES

Cats and dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Cutaneous use

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once broached,/opened, use by…
Shelf-life after first opening the container: 1 year

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

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

For animal treatment only.

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 01656/4058

17. MANUFACTURER'S BATCH NUMBER

Lot:

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

PACKAGE LEAFLET
Flevox 2.5 mg/ml cutaneous spray, solution for cats and dogs

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

1 ml of clear, colourless liquid contains 2.5 mg of fipronil.

4. INDICATION(S)

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 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 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. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
Among the very rare suspected adverse reactions, transient cutaneous reactions erythema, pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use.

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

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

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats and dogs.

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

Route of administration: mechanical pump spray for external 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.

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 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 product into the coat. Allow to dry naturally. Do not towel dry.

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.

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

Puppies and kittens from 2 days of age may be safely treated.

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 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 product. Monthly treatment is recommended when more frequent shampooing is carried out.

10. WITHDRAWAL PERIOD(S)

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 label after (EXP). The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 1 year

12. SPECIAL WARNING(S)

Do not exceed the recommended dosage.
Allow treated animals to dry in a well ventilated room
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 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 product.
The product is not suitable for direct treatment of the environment.
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.
Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.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. For external use only.

Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit.
The formulation is very well tolerated by puppies following treatment of the lactating bitch.
Data are not available on treatment of pregnant queens or nursing queens.

The risk of experiencing adverse effects (see section 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.

User warnings
This product can cause mucous membrane and eye irritation. Therefore, contact of the product with mouth and eyes should be avoided. After accidental ocular exposure the eye should be rinsed carefully with plain water.
Operators with a known hypersensitivity to the active substance or alcohol or with asthmashould avoid contact with the product. 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.
Wear PVC or nitrile gloves during treatment of animals.
It is recommended to wear a waterproof apron for the protection of clothing. If clothing becomes heavily wetted with the 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 product. Do not use 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.

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 may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2017

15. OTHER INFORMATION

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.
Not all pack sizes may be marketed.

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

Approved: 05 September 2017