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

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Fipronil .....2.5 mg

Excipients:

Qualitative composition of excipients and other constituents
Copovidone
Isopropyl Alcohol
Purified water

Clear, colourless to slightly yellow solution

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

The treatment and prevention of flea infestation (*Ctenocephalides spp.*) and tick infestation (*Ixodes ricinus, Rhipicephalus sanguineus*) in dogs.
The treatment and prevention of flea infestation (*Ctenocephalides spp.*) and tick infestation (*Rhipicephalus spp, Ixodes ricinus, Ixodes scapularis, Dermacentor variabilis*) in cats.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

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

Avoid contact with the animal's eyes.
Do not exceed the recommended dosage.
Do not spray directly onto areas of broken skin.
Allow treated animals to dry in a well ventilated room (see also section 3.5))

For optimum efficacy, it is not recommended to bathe or shampoo animals within the two days period prior to treatment or within the two days period following treatment.

3.5 Special precautions for use

Special precautions for safe use in target species:

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 transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to insecticides or alcohol should avoid contact with the veterinary medicinal product.
This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wear PVC or nitrile gloves during treatment of animals. In case of contact with skin, wash hands with soap and water.
In case of accidental ocular exposure, rinse the eyes carefully with plain 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.

Do not smoke, drink or eat during application.

Wash hands after use.

Special precautions for the protection of the environment:

Fipronil is toxic for aquatic organisms. Treated dogs should not be allowed to enter surface water for 2 days after treatment, to avoid adverse effects on aquatic organisms.

3.6 Adverse events

Dogs, cats:

Very rare (<1 animal /10,000 animals treated, including isolated reports):	Application site reactions (erythema[1], pruritus[1], alopecia[1]) Hypersalivation[2], vomiting Respiratory signs Hyperaesthesia[3], depression[3], neurological signs[3]

[1] Transient
[2] If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
[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

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects of fipronil.
The formulation is very well tolerated by puppies following treatment of the lactating bitch. Can be used during pregnancy and lactation.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in queens. Use only in accordance with 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

Cutaneous use.

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

Dosage:
In order to dampen the coat down to the skin, apply 3 to 6 ml per kg bodyweight, (7.5 to 15 mg of active ingredient per kg bodyweight), depending on the length of hair: 3 ml/kg bw for animals of short hair until 6 ml/kg for animals of long hair.
This dosage can be achieved with 6 to 12 pump applications per kg bodyweight of the 100 ml presentation, or 2 to 4 pump applications of the 250 ml or 500 ml presentation.

As part of a treatment strategy for Flea Allergy Dermatitis it is recommended a monthly application of allergic animals and all animals that live jointly them.

The veterinary medicinal product is active for up to 2 months against fleas It is effective against tick infestations for up one month. In case of biting lice, if it is necessary, repeat the treatment after four weeks of the first application.

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

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. Allow to dry naturally. Do not towel dry.

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 is an insecticide and acaricide from 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 the membrane. This results in uncontrolled activity of the central nervous system and death in insects and acarids.

Fipronil exhibits insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp) in the dog and the cat and lice (*Trichodectes canis)* in the dog and *(Felicola subrustratus)* in the cat. Fipronil also presents an acaricidal activity against the ticks (*Dermacentor variabilis, Rhipicephalus* spp*, Ixodes scapularis, Ixodes ricinus)*, in the dog and the cat.

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

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 1 year

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

100 ml filled in high density polyethylene white opaque bottle hermetically closed with a mechanical pump spray delivering 0.5 ml per spray (plunger in low density polyethylene).

250 ml filled in high density polyethylene white opaque bottle hermetically closed with a mechanical trigger pump delivering 1.5 ml per spray (plunger in polypropylene).

500 ml filled in high density polyethylene white opaque bottle hermetically closed with a mechanical trigger pump delivering 1.5 ml per spray (plunger in polypropylene).

Package sizes:
Bottle of 100 ml
Bottle of 250 ml
Bottle of 500 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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.

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

LABORATORIOS CALIER, S.A. [BG, DE, EE, EL, ES, IT, LV]
CALIER PORTUGAL S.A. [PT]

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

BG, EE, ES, IT, LV: Veterinary medicinal product not subject to prescription.
DE, EL: Veterinary medicinal product subject to prescription.

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

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100, 250 or 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EFFINOL 2.5 mg/ml cutaneous spray, solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Fipronil ..... 2.5 mg

3. PACKAGE SIZE

100 ml
250 ml
500 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATION(S)

For products not subject to veterinary prescription.

The treatment and prevention of flea infestation (*Ctenocephalides* spp.) and tick infestation (*Ixodes ricinus, Rhipicephalus sanguineus*) in dogs.
The treatment and prevention of flea infestation (*Ctenocephalides* spp.) and tick infestation (*Rhipicephalus spp, Ixodes ricinus, Ixodes scapularis, Dermacentor variabilis*) in cats.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

6. ROUTES OF ADMINISTRATION

Cutaneous use.

7. WITHDRAWAL PERIOD(S)

8. EXPIRY DATE

EXP {month/year}:
Once opened, use within 1 year.

Once opened use by:…

9. SPECIAL STORAGE PRECAUTIONS

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

LABORATORIOS CALIER, S.A. [BG, DE, EE, EL, ES, IT, LV]
CALIER PORTUGAL S.A. [PT]

14. MARKETING AUTHORISATION NUMBER(S)

15. MANUFACTURER’S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:
Fipronil ..... 2.5 mg

Clear, colourless to slightly yellow solution.

3. Target species

Dogs andcats.

4. Indications for use

The treatment and prevention of flea infestation (*Ctenocephalides* spp.) and tick infestation (*Ixodes ricinus, Rhipicephalus sanguineus*) in dogs.
The treatment and prevention of flea infestation (*Ctenocephalides* spp.) and tick infestation (*Rhipicephalus spp, Ixodes ricinus, Ixodes scapularis, Dermacentor variabilis*) in cats.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

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:

Avoid contact with the animal's eyes.
Do not exceed the recommended dosage
Do not spray directly onto areas of broken skin
Allow treated animals to dry in a well ventilated room
For optimum efficacy, it is not recommended to bathe or shampoo animals within the two days period prior to treatment or within the two days period following treatment.

Special precautions for safe use in the target species:

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 transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

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

People with known hypersensitivity to insecticides or alcohol should avoid contact with the veterinary medicinal product.

This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided. Spray animals in the open air or a well ventilated room. Avoid contents coming into contact with the fingers. Wear PVC or nitrile gloves during treatment of animals. In case of contact with skin, wash hands with soap and water. In case of accidental ocular exposure rinse the eyes carefully with plain 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.

Do not smoke, drink or eat during application.

Wash hands after use.

Special precautions for the protection of the environment:

Fipronil is toxic for aquatic organisms. Treated dogs should not be allowed to enter surface water for 2 days after treatment, to avoid adverse effects on aquatic organisms.

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects of fipronil
The formulation is very well tolerated by puppies following treatment of the lactating bitch. Can be used during pregnancy and lactation.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in queens. Use only in accordance with the benefit-risk assessment by the responsible veterinarian.

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.

7. Adverse events

Dogs, cats:

Very rare (<1 animal /10,000 animals treated, including isolated reports):	Application site reactions (erythema[1], pruritus[1], alopecia[1]) Hypersalivation[2], vomiting Respiratory signs Hyperaesthesia[3], depression[3], neurological signs[3]

[1] Transient
[2] If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
[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.

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

Cutaneous use.

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

Dosage:
In order to dampen the coat down to the skin, apply 3 to 6 ml per kg bodyweight, (7.5 to 15 mg of active ingredient per kg bodyweight), depending on the length of hair: 3 ml/kg bw for animals of short hair until 6 ml/kg for animals of long hair.
This dosage can be achieved with 6 to 12 pump applications per kg bodyweight of the 100 ml presentation, or 2 to 4 pump applications of the 250 ml or 500 ml presentation.

As part of a treatment strategy for Flea Allergy Dermatitis it is recommended a monthly application of allergic animals and all animals that live jointly them.

The veterinary medicinal product is active for up to 2 months against fleas. It is effective against tick infestations for up one month. In case of biting lice, if it is necessary, repeat the treatment after four weeks of the first application.

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

9. Advice on correct 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. Allow to dry naturally. Do not towel dry

10. Withdrawal periods

Not applicable

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
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 immediate packaging: 1 year

12. Special precautions for the 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.

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. These measures should help to protect deh environmental.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. .

13. Classification of veterinary medicinal products

BG, EE, ES, IT, LV: Veterinary medicinal product not subject to prescription.
DE, EL: Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Package sizes:
Bottle of 100 ml
Bottle of 250 ml
Bottle of 500 ml

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).

16. Contact details

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

LABORATORIOS CALIER, S.A. [BG, DE, EE, EL, ES, IT, LV]
Calle Barcelonés 26
Polígono Industrial del Ramassà
08520 Les Franqueses del Vallès
Barcelona
Spain

CALIER PORTUGAL, S.A. [PT]
Centro Empresarial Sintra-Estoril II
Rua Pé de Mouro, Edifício
C Estrada de Albarraque
2710 - 335 Sintra
Portugal

Manufacturer responsible for batch release:

LABORATORIOS CALIER S.A.

C. Barcelonès, 26
Polígono Industral del Ramassà
08520 Les Franqueses del Vallès
Barcelona
Spain

<Local representatives <and contact details to report suspected adverse reactions>:>

[To be completed nationally]

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