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:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Cutaneous spray, solution.
Clear, colourless to slightly yellow solution

4. CLINICAL PARTICULARS

4.1 Target species
Dogs and cats

4.2 Indications for use, specifying the 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 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*).

4.3 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..

4.4 Special warnings for each target species
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 4.5 ii))
For optimum efficacy, it is not recommended to bathe or shampoo animals within the two day period prior to treatment or within the two day period following treatment.

4.5 Special precautions for use
Special precautions for use in animals
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

This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided.
People with known hypersensitivity to insecticides or alcohol should avoid contact with the veterinary medicinal product.. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.
After accidental ocular exposure the eye should be rinsed carefully with plain water.

Spray animals in the open air or a well ventilated room. Do not breathe spray.

Wear PVC or nitrile gloves during treatment of animals.

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 hand after use.

Other precautions

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.

4.6 Adverse reactions (frequency and seriousness)

Transient cutaneous reactions such as erythema, pruritus or alopecia have been reported after use among the very rare suspected adverse reactions,.

Hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been very rarely observed after use. If licking occurs, a brief period of hypersalivation may be very rarely observed due mainly to the nature of the carrier.

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).

Do not overdose.

4.7 Use during pregnancy, lactation or lay

Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit. Can be used during pregnancy.
The formulation is very well tolerated by puppies following treatment of the lactating bitch. Can be used during 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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Cutaneous use

Animals should be weighed accurately prior to treatment.

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 product is active for up to 2 month 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
The risk of experiencing adverse effects (see section 4.6) 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.

4.11 Withdrawal period(s)
Not applicable

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: Ectoparasiticides for topical use
ATCvet code: QP53AX15.

5.1 Pharmacodynamic properties
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.

5.2 Pharmacokinetic particulars
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Copovidone
Isopropyl Alcohol
Water, purified

6.2 Major incompatibilities
Not applicable.

6.3 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

6.4. Special precautions for storage
This veterinary medicinal product does not require any special storage conditions.

6.5 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 mlNot all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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 container.

7. MARKETING AUTHORISATION HOLDER
LABORATORIOS CALIER, S.A.
Barcelonès, 26 – PI del Ramassar
08520 Les Franqueses del Vallès
(Barcelona)

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of last renewal:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE