B. PACKAGE LABEL - LEAFLET

PACKAGE LABEL - LEAFLET:
EFFINOL 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:
LABORATORIOS CALIER, S.A.
Barcelonès, 26 – Pla del Ramassà
08520 Les Franqueses del Vallès
(Barcelona)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Each ml contains

Active substance:
Fipronil ..... 2.5 mg

4. INDICATION(S)

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*).

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

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.

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

Dogs and cats

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

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.

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 PERIOD

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 {abbreviation used for expiry date}. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 1 year

12. SPECIAL WARNING(S)

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
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.

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.

Pregnancy and lactation:
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.

Overdose (symptoms, emergency procedures, antidotes):
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment
Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

Not all pack sizes may be marketed