

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{NATURE/TYPE} 100, 250 and 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Active substance:

Fipronil 2.5 mg

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

100 ml
250 ml
500 ml

5. TARGET SPECIES

Dogs and cats

6. 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*).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year};
Once opened use by:...

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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

LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26 (Pla de Ramassà)
08520 Les Franqueses del Vallès, (Barcelona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch {number}