Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

EFFINOL 2.5 mg/ml CUTANEOUS SPRAY SOLUTION FOR CATS AND DOGS

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0214/001/DC
Name, strength and pharmaceutical form	EFFINOL 2.5 mg/ml CUTANEOUS SPRAY SOLUTION FOR CATS AND DOGS
Applicant	Laboratorios Calier, S.A
Active substance(s)	Fipronil
ATC Vet code	QP53AX15
Target species	Dog Cat
Indication 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 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*).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	23/04/2014
Date product first authorised in the Reference Member State (MRP only)	NA
Concerned Member States for original procedure	IT, BG, PT, LV, DE, EE

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.
The product is safe for the user, and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

Composition

The product contains 2.5 mg/ml of Fipronil and copovidone, isopropyl alcohol and purified water as excipients.

The product is packaged in high density polyethylene white opaque bottles (multiple dose containers). The particulars of the containers and controls performed are provided and conform to the regulation.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

Control of Starting Materials

The active substance is Fipronil, an established substance manufactured in accordance with the principles of good manufacturing practices.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

EFFINOL 2,5 mg/ml cutaneous spray, solution for cats and dogs is submitted as a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of safety tests are not required.

The safety aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users, the environment.

III.A Safety Testing

Pharmacological Studies

The applicant is not required to provide the results of pharmacological tests because all these data are in the documentation that support the reference product.

Toxicological Studies

The applicant is not required to provide the results of toxicological tests because all these data are in the documentation that support the reference product.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the measures are identical to the reference product.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The assessment concluded that the exclusion of non-food animals in question 3.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT (EFFICACY)

EFFINOL 2,5 mg/ml cutaneous spray, solution for cats and dogs is a generic application according to Article 13, and bioequivalence with reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

The applicant has provided bibliographical data to show that the bioequivalence with reference product has been demonstrated.

IV.B Clinical Studies

The applicant has not considered necessary efficacy studies since the generic product has the identical composition to the reference product and the bioequivalence has been demonstrated.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the veterinary Heads of Agencies website (www.hma.eu).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

None