DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

SINERGEL 50 MG SPOT-ON SOLUTION FOR CATS

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0386/001/DC
Name, strength and pharmaceutical form	Sinergel 50 mg Spot-On solution for cats
Applicant	SINERGIC CHEMICAL S.L.
Active substance(s)	Fipronil
ATC Vetcode	QP53AX15
Target species	Cats
Indication for use	'Treatment and prevention of flea infestations (*Ctenocephalides felis*). Fleas present on the animal at the time of the veterinary medicinal product application will be killed within 48 hours. The veterinary medicinal product has persistent insecticidal efficacy lasting for 4 weeks against *Ctenocephalides felis* fleas. Treatment and prevention of tick infestations *(Rhipicephalus turanicus*). Ticks present on the animal at the time of the veterinary medicinal product application will be killed within 48 hours. The veterinary medicinal product has persistent acaricidal efficacy for 4 weeks against *Rhipicephalus turanicus* ticks.'

MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	18/11/20
Date product first authorised in the ReferenceMemberState (MRP only)	-
Concerned Member States for original procedure	PT

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

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

A. Qualitative and quantitative particulars

The product contains fipronil (50 mg/pipette) as active substance, and BHT and BHA as antioxidants. Other ingredients are povidone, polysorbate 80, ethanol 96%, diethylene glycol monoethyl eter.

The container/closure system is white opaque plastic spot-on pipettes of COEX-High Density Polyethylene-Extrusion material. The choice of the container closure system is adequate for the intended use of the medicinal product.

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

B. 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.

C. Control of Starting Materials

The active substance is fipronil, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

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.

The information on the active substance is provided according to the Active Substance Master File (ASMF) procedure.

Confirmation is provided regarding compliance of the finished product with the current Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products.

D. Control on intermediate products

Not applicable.

E. 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.

F. Stability

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

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life (3 years) when stored under the approved conditions.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT

As this is a hybrid application according to Article 13.3, bibliographic information on the pharmaceutical effects of fipronil have been provided.

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 and the environment.

III.A Safety Testing

Pharmacological Studies

In accordance with the requirements for this type of application, Article 13 (3), bibliographic information on the pharmacological effects of fipronil has been provided.

Both the candidate and reference products are spot-on solutions and they are used in the same species, for the same indications, in the same doses and using the same administration method. It was accepted that the candidate formulation is sufficiently similar to the reference fomulation in terms of active substance and excipients.

Toxicological Studies

In accordance with the requirements for this type of application, Article 13 (3), bibliographic information on the toxicological effects of fipronil has been provided. As bioequivalence with the reference product is accepted, results of toxicological tests are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the risk to the user associated with the use of this product is identical to that of the reference product and the user warnings proposed are in accordance with those of the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

Given that fipronil may be toxic to aquatic organisms a recommendation has been included. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The applicant has conducted a controlled target animal tolerance study using multiples of the recommended dose in the target species. A placebo was used as a control. All doses were administered by topic route on 3 occasions.
Parameters evaluated were weight, behaviour, physical conditions, blood biochemistry, hematology and urinalyses.
No adverse effects were seen following doses up to 5 times the recommended dose.
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

Resistance

The bibliography provided suggests that there is no problem in the development of resistance and no lack of efficacy due to development of resistance is expected.

Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

Laboratory Trials

The applicant has conducted two dose confirmation studies blinded, randomised, negative controlled that support the efficacy of the product in accordance with the Summary of Product Characteristics.

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.

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