FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
AGENCE NATIONALE DU MEDICAMENT VETERINAIRE
14 rue Claude Bourgelat –
Parc d'activités de la grande Marche –
Javené – CS 70611 –
35306 FOUGERES

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Slais 26.8 mg/240 mg spot-on solution for very small dogs
Slais 67 mg/600 mg spot-on solution for small dogs
Slais 134 mg/1200 mg spot-on solution for medium dogs
Slais 268 mg/2400 mg spot-on solution for large dogs
Slais 402 mg/3600 mg spot-on solution for very large dogs

DATE: 2020.08.20.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0421/001-005/DC
Name, strength and pharmaceutical form	Slais 26.8 mg/240 mg spot-on solution for very small dogs Slais 67 mg/600 mg spot-on solution for small dogs Slais 134 mg/1200 mg spot-on solution for medium dogs Slais 268 mg/2400 mg spot-on solution for large dogs Slais 402 mg/3600 mg spot-on solution for very large dogs
Applicant	ALFAMED 13ème rue – L.I.D. 06517 Carros France
Active substance(s)	Fipronil & Permethrin
ATC Vetcode	QP53AC54
Target species	Dogs
Indication for use	In dogs, to be used against infestations with fleas and/or ticks when repellent (anti-feeding) activity is also necessary against sand-flies and/or mosquitoes. <u>Fleas:</u> Treatment and prevention of infestations by fleas (Ctenocephalides felis). Fleas on dogs are killed within 24 hours following treatment. One treatment provides persistent efficacy against new infestations with adult fleas for four weeks. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this condition has previously been diagnosed by a veterinarian.

	<u>Ticks:</u> Treatment of infestations with Ixodes ricinus ticks. One application provides four weeks persistent acaricidal efficacy against tick infestations (Ixodes ricinus, Dermacentor reticulatus and Rhipicephalus sanguineus). If ticks of some species (Dermacentor reticulatus or Rhipicephalus sanguineus) are present at the time of application, not all ticks may be killed within 48 hours. <u>Sand-flies and mosquitoes:</u> One treatment provides repellent (anti-feeding) activity against sand-flies (Phlebotomus perniciosus) and against mosquitoes (Culex pipiens, Aedes aegypti) for four weeks.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website https://www.anses.fr/en/thematique/veterinary-medicine-anmv

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of application	Informed consent application in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Date of completion of the application	12/06/2020
Concerned Member States for procedure	IT

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of these products are identical to “Effitix Spot-on Solution for dogs” products (reference products).

II. QUALITY ASPECTS

A. Composition

The product contains the following amounts of the active substances fipronil and permethrin respectively 26.8 mg / 240 mg; 67 mg / 600 mg; 134 mg / 1200 mg; 268 mg / 2400 mg and 402 mg / 3600 mg.

Dog weight	Fipronil (mg)	Permethrin (mg)
1.5-4 kg	26.8	240
4-10 kg	67	600
10-20 kg	134	1200
20-40 kg	268	2400
40-60 kg	402	3600

The excipients are Butylhydroxyanisole (E320), Butylhydroxytoluene (E321), benzyl alcohol (E1519) and diethylene glycol monoethyl ether.

The packaging of the finished product is as described on the SPC. 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.

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 substances are permethrin and fipronil, established active substances.
The active substance specifications are considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

Not applicable.

F. 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.

G. Stability

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

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

See part IV.A

Toxicological Studies

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

User Safety

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, a user safety assessment is not required.

Environmental Risk Assessment

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, an environmental risk assessment is not required.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, pre-clinical studies are not required.

Tolerance in the Target Species of Animals

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, tolerance studies are not required.

IV.B Clinical Studies

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, clinical studies are not required.
The efficacy claims for this product are equivalent to those of the reference product.

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 (https://www.hma.eu/veterinarymedicines.html).

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>