Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Fiprofile 26.8 mg/240 mg Spot-On Solution for Very Small Dogs
Fiprofile 67 mg/600 mg Spot-On Solution for Small Dogs
Fiprofile 134 mg/1200 mg Spot-On Solution for Medium Dogs
Fiprofile 268 mg/2400 mg Spot-On Solution for Large Dogs
Fiprofile 402 mg/3600 mg Spot-On Solution for Very Large Dogs

Date Created: June 2018

PuAR correct as of 08/04/19 when RMS was transferred to IT.
Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0673/001/DC UK/V/0673/002/DC UK/V/0673/003/DC UK/V/0673/004/DC UK/V/0673/005/DC
Name, strength and pharmaceutical form	Fiprofile 26.8 mg/240 mg Spot-On Solution for Very Small Dogs Fiprofile 67 mg/600 mg Spot-On Solution for Small Dogs Fiprofile 134 mg/1200 mg Spot-On Solution for Medium Dogs Fiprofile 268 mg/2400 mg Spot-On Solution for Large Dogs Fiprofile 402 mg/3600 mg Spot-On Solution for Very Large Dogs
Applicant	Alfamed 13ème Rue – L.I.D Carros Cedex 06517 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. Fleas: 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. Ticks: 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* and *Rhipicephalus sanguineus*) are present at the time of application, not all ticks may be killed within 48 hours. Sand-flies and mosquitoes: 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 Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed Consent applications in accordance with Article 13 (c) of Directive 2001/82/EC, as amended.
Date of conclusion of the decentralised procedures	11th May 2018.
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	Italy.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of these products are identical to the Effitix series of products, which contain the same quantities of active substance:

Effitix 26.8 mg/240 mg Spot-On Solution for Very Small Dogs

Effitix 67 mg/600 mg Spot-On Solution for Small Dogs

Effitix 134 mg/1200 mg Spot-On Solution for Medium Dogs

Effitix 268 mg/2400 mg Spot-On Solution for Large Dogs

Effitix 402 mg/3600 mg Spot-On Solution for Very Large Dogs

II. 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 benefit/risk profile of the product(s) is favourable and the product has been refused.

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 Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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