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

Perfikan 26.8 mg/240 mg spot-on solution for very small dogs (UK, PT)
Caniguard duo 26.8 mg/240 mg spot-on solution for very small dogs (ES, IT)

Perfikan 67 mg/600 mg spot-on solution for small dogs (UK, PT)
Caniguard duo 67 mg/600 mg spot-on solution for small dogs (ES, IT)

Perfikan 134 mg/1200 mg spot-on solution for medium dogs (UK, PT)
Caniguard duo 134 mg/1200 mg spot-on solution for medium dogs (ES, IT)

Perfikan 268 mg/2400 mg spot-on solution for large dogs (UK, PT)
Caniguard duo 268 mg/2400 mg spot-on solution for large dogs (ES, IT)

Perfikan 402 mg/3600 mg spot-on solution for very large dogs (UK, PT)
Caniguard duo 402 mg/3600 mg spot-on solution for very large dogs (ES, IT)

Date Created: July 2016

PuAR correct as of 11/09/18 when RMS was transferred to PT. Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0599/001/DC UK/V/0599/002/DC UK/V/0599/003/DC UK/V/0599/004/DC UK/V/0599/005/DC
Name, strength and pharmaceutical form	Perfikan 26.8 mg/240 mg spot-on solution for very small dogs (UK, IT, PT) Perfikan 67 mg/600 mg spot-on solution for small dogs (UK, IT, PT) Perfikan 134 mg/1200 mg spot-on solution for medium dogs (UK, IT, PT) Perfikan 268 mg/2400 mg spot-on solution for large dogs (UK, IT, PT) Perfikan 402 mg/3600 mg spot-on solution for very large dogs (UK, IT, PT)
Applicant	Alfamed 13ème Rue – L.I.D. 06517 Carros Cedex 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 application in accordance with Article 13 (C) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	5th May 2016.
Date product first authorised in the Reference Member State (MRP only)	No applicable.
Concerned Member States for original procedure	Italy, Portugal, Spain.

I. SCIENTIFIC OVERVIEW

The quality/safety/efficacy aspects of these products are identical to 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 and 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.

.

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.

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

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.

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