Veterinary Medicines Directorate

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

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A PROPOSED VETERINARY MEDICINAL PRODUCT

Effipro Duo 100 mg/120 mg Spot-on Solution for Very Large Cats
Effipro Due 50 mg/60 mg Spot-on Solution for Cats
Effipro Duo 67 mg/20 mg Spot-on Solution for Small Dogs
Effipro Duo 134/40 mg Spot-on Solution for Medium Dogs
Effipro Duo 268 mg/80 mg Spot-on Solution for Large Dogs
Effipro Duo 403 mg/120 mg Spot-on Solution for Very Large Dogs

Date Created: June 2019

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Effipro Duo 100 mg/120 mg Spot-on Solution for Very Large Cats Effipro Due 50 mg/60 mg Spot-on Solution for Cats Effipro Duo 67 mg/20 mg Spot-on Solution for Small Dogs Effipro Duo 134/40 mg Spot-on Solution for Medium Dogs Effipro Duo 268 mg/80 mg Spot-on Solution for Large Dogs Effipro Duo 403 mg/120 mg Spot-on Solution for Very Large Dogs
Applicant	Virbac Limited Woolpit Business Park Windmill Avenue Woolpit, Bury St Edmunds Suffolk IP30 9UP United Kingdom
Active substance	Fipronil, Pyriproxyfen
ATC Vetcode	QP53AX65
Target species	Dogs, cats
Indication for use	Dogs Against fleas: Treatment and prevention of infestations by fleas (*Ctenocephalides felis*). One treatment prevents further infestations for 7 weeks. Prevention of the multiplication of fleas by preventing flea eggs developing into adult fleas for 12 weeks after application. The product can be used as part of a treatment

	strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon. Against ticks: Treatment of infestations by ticks (*Ixodes ricinus*). One treatment provides persistent acaricidal efficacy for 2 weeks against *Ixodes ricinus*, and for 4 weeks against *Dermacentor reticulatus* and *Rhipicephalus sanguineus*. If ticks of some species (*Dermacentor reticulatus, Rhipicephalus sanguineus*) are present at the time of application, not all ticks may be killed within 48 hours. <u>Cats</u> In cats, to be used against infestations with fleas alone or in association with ticks. Against fleas: Treatment and prevention of infestations by fleas (*Ctenocephalides felis*). One treatment prevents further infestations for 5 weeks. Prevention of the multiplication of fleas by preventing flea eggs developing into adult fleas for 12 weeks after application. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon. Against ticks: Treatment of infestations by ticks (*Ixodes ricinus* and *Rhipicephalus turanicus*). One treatment provides persistent acaricidal efficacy for one week. If ticks are present at the time of application, not all ticks may be killed within 48 hours.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	National informed consent applications in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	20th June 2019

I. SCIENTIFIC OVERVIEW

The quality/safety/efficacy aspects of this product are identical to the comparable Fipronil Pyriproxifen Virbac spot-one products.

II OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrated that when the products are used in accordance with the Summary of Product Characteristics, the benefit/risk profile of the products 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.

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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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