Veterinary Medicines Directorate

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

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Ectoline Duo 268 mg/80 mg Spot-on Solution for Large Dogs

Date Created: December 2018

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Ectoline Duo 268 mg/80 mg Spot-on Solution for Large Dogs, Spot-on solution
Applicant	Alfamed, 13'eme rue - L.I.D, Carros Cedex, 06517, France
Active substances	Fipronil and Pyriproxyfen
ATC Vetcode	QP53AX65
Target species	Dogs
Indication for use	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.

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 13c of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	30th April 2019

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Fipronil Pyriproxyfen Virbac 268 mg/80 mg Spot-on Solution for 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 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)

As the application was refused, there are no post-authorisation assessments.