



**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 67 mg/20 mg Spot-on Solution for Small Dogs**

**Date Created: May 2019**

## MODULE 1

### PRODUCT SUMMARY

Name, strength and pharmaceutical form	Ectoline Duo 67 mg/20 mg Spot-on Solution for Small 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	<p>To be used against infestations with fleas alone or in association with ticks.</p> <p><u>Against fleas:</u> Treatment and prevention of infestations by fleas (<i>Ctenocephalides felis</i>). 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.</p> <p><u>Against ticks:</u> Treatment of infestations by ticks (<i>Ixodes ricinus</i>). One treatment provides persistent acaricidal efficacy for 2 weeks against <i>Ixodes ricinus</i>, and for 4 weeks against <i>Dermacentor reticulatus</i> and <i>Rhipicephalus sanguineus</i>. If ticks of some species (<i>Dermacentor reticulatus</i>, <i>Rhipicephalus sanguineus</i>) are present at the time of application, not all ticks may be killed within 48 hours</p>

## **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](http://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	30 <sup>th</sup> April 2019

#### **I. SCIENTIFIC OVERVIEW**

The quality/safety/efficacy aspects of this product are identical to Fipronil Pyriproxyfen Virbac 67 mg/20 mg Spot-on Solution for Small 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](http://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](http://www.gov.uk/check-animal-medicine-licensed))