

**FRENCH AGENCY FOR FOOD, ENVIRONMENTAL AND OCCUPATIONAL
HEALTH SAFETY**

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

**14 RUE CLAUDE BOURGELAT – PARC D’ACTIVITES DE LA GRANDE MARCHÉ
JAVENE – CS 70611 – 35306 FOUGERES**

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

FIPRONIL PERMETHRIN ALFAMED 26.8 MG/240 MG SPOT-ON SOLUTION FOR VERY SMALL DOGS

FIPRONIL PERMETHRIN ALFAMED 67 MG/600 MG SPOT-ON SOLUTION FOR SMALL DOGS

FIPRONIL PERMETHRIN ALFAMED 134 MG/1200 MG SPOT-ON SOLUTION FOR MEDIUM DOGS

FIPRONIL PERMETHRIN ALFAMED 268 MG/2400 MG SPOT-ON SOLUTION FOR LARGE DOGS

FIPRONIL PERMETHRIN ALFAMED 402 MG/3600 MG SPOT-ON SOLUTION FOR VERY LARGE DOGS

24 November 2023

FIPRONIL PERMETHRIN ALFAMED SPOT-ON SOLUTION FOR DOGS	FR/V/0469/001-005/DC
ALFAMED	DCP
Publicly available assessment report	

PRODUCT SUMMARY

EU procedure number	FR V 0469 001-005 DC
Name, strength and pharmaceutical form	<p>FIPRONIL PERMETHRIN ALFAMED 26.8 MG/240 MG SPOT-ON SOLUTION FOR VERY SMALL DOGS</p> <p>FIPRONIL PERMETHRIN ALFAMED 67 MG/600 MG SPOT-ON SOLUTION FOR SMALL DOGS</p> <p>FIPRONIL PERMETHRIN ALFAMED 134 MG/1200 MG SPOT-ON SOLUTION FOR MEDIUM DOGS</p> <p>FIPRONIL PERMETHRIN ALFAMED 268 MG/2400 MG SPOT-ON SOLUTION FOR LARGE DOGS</p> <p>FIPRONIL PERMETHRIN ALFAMED 402 MG/3600 MG SPOT-ON SOLUTION FOR VERY LARGE DOGS</p>
Applicant	<p>ALFAMED</p> <p>13e Rue</p> <p>06510 Carros, France</p>
Active substance(s)	<p>Fipronil</p> <p>Permethrin</p>
ATC vetcode	QP53AC54
Target species	Dogs
Indication for use	<p>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.</p> <p>Fleas: Treatment and prevention of infestations by fleas (<i>Ctenocephalides felis</i>). 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.</p> <p>Ticks: Treatment of infestations with <i>Ixodes ricinus</i> ticks. One application provides four weeks persistent acaricidal efficacy against tick infestations (<i>Ixodes ricinus</i>, <i>Dermacentor reticulatus</i> and <i>Rhipicephalus sanguineus</i>).</p>

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	<p>If ticks of some species (<i>Dermacentor reticulatus</i> or <i>Rhipicephalus sanguineus</i>) are present at the time of application, not all ticks may be killed within 48 hours.</p> <p>Sand-flies and mosquitoes: One treatment provides repellent (anti-feeding) activity against sand-flies (<i>Phlebotomus perniciosus</i>) and against mosquitoes (<i>Culex pipiens</i>, <i>Aedes aegypti</i>) for four weeks. 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.</p>
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PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

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SUMMARY OF ASSESSMENT

Legal basis of original application	Application in accordance with Article 21 - Informed consent application (Regulation 2019/6)
Date of completion of the original decentralised procedure	22/11/2023
Concerned Member States for original procedure	FR, ES, IT

1. SCIENTIFIC OVERVIEW

These applications were submitted in accordance with Article 21 of Regulation (EU) 2019/6, a so called informed consent application.

The cross-referred product (that is 'the already authorized veterinary medicinal product or originator VMP') is:

Effitix 26.8mg/240mg spot-on solution for very small dogs (FR/V/0371/001/DC, previously UK/V/0502/001/DC) authorized on 03/06/2014;

Effitix 67mg/600mg spot-on solution for small dogs (FR/V/0371/002/DC, previously UK/V/0502/002/DC) authorized on 03/06/2014;

Effitix 134mg/1200mg spot-on solution for medium dogs (FR/V/0371/003/DC, previously UK/V/0502/003/DC) authorized on 03/06/2014;

Effitix 268mg/2400mg spot-on solution for large dogs (FR/V/0371/004/DC, previously UK/V/0502/004/DC) authorized on 03/06/2014;

Effitix 402mg/3600mg spot-on solution for very large dogs (FR/V/0371/005/DC, previously UK/V/0502/005/DC) authorized on 03/06/2014.

This cross-referred product is marketed by the marketing authorisation holder Virbac.

2. QUALITY DOCUMENTATION

The quality aspects of this veterinary medicinal product are identical to the cross-referred product Effitix.

Please refer to the public assessment report of original VMP.

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3. SAFETY DOCUMENTATION

The safety aspects of this veterinary medicinal product are identical to the cross-referred product Effitix.

Please refer to the public assessment report of original VMP.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

The efficacy aspects of this veterinary medicinal product are identical to the cross-referred product Effitix.

Please refer to the public assessment report of original VMP.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

Given the legal basis of this application (Article 21 of Regulation (EU) 2019/6), the benefit-risk balance is favourable as for the cross-referred product.