



**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 PYRIPROXYFEN VIRBAC 50 MG/60 MG SPOT-ON SOLUTION FOR CATS /  
FIPRONIL PYRIPROXYFEN VIRBAC 100 MG/120 MG SPOT-ON SOLUTION FOR VERY  
LARGE CATS**

**24 November 2023**

FIPRONIL PYRIPROXYFEN VIRBAC SPOT-ON SOLUTION FOR CATS / VERY LARGE CATS	FR/V/0473/001-002/DC
ALFAMED	DCP
Publicly available assessment report	

## PRODUCT SUMMARY

EU procedure number	FR/V/0473/001-002/DC
Name, strength and pharmaceutical form	FIPRONIL PYRIPROXYFEN VIRBAC 50 MG/60 MG SPOT-ON SOLUTION FOR CATS FIPRONIL PYRIPROXYFEN VIRBAC 100 MG/120 MG SPOT-ON SOLUTION FOR VERY LARGE CATS
Applicant	ALFAMED 13e Rue 06510 Carros, France
Active substance(s)	Fipronil Pyriproxyfen
ATC vetcode	QP53AX65
Target species	Cats
Indication for use	<p>In cats, to be used against infestations with fleas alone or in association with ticks.</p> <p>Against fleas: Treatment and prevention of infestations by fleas (<i>Ctenocephalides felis</i>). 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 veterinary medicinal 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>Against ticks: Treatment of infestations by ticks (<i>Ixodes ricinus</i> and <i>Rhipicephalus turanicus</i>). 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:

Effipro Duo 50 mg/60 mg spot-on solution for cats (FRV/0402/005/DC, previously UK/V/0543/005/DC) authorized on 22/07/2015; Effipro Duo 100 mg/120 mg spot-on solution for very large cats (FR/V/0402/006/DC, previously UK/V/0402/006/DC) authorized on 22/07/2015.

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 Effipro Duo.

Please refer to the public assessment report of original VMP.

### 3. SAFETY DOCUMENTATION

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

Please refer to the public assessment report of original VMP.

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#### **4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)**

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

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.