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AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

FRENCH AGENCY FOR FOOD, ENVIRONNEMENTAL AND OCCUPATIONAL HEALTH SAFETY

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

14 RUE CLAUDE BOURGELAT – PARC D'ACTIVITES DE LA GRANDE MARCHE JAVENE – CS 70611 – 35306 FOUGERES

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

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

24 November 2023

PRODUCT SUMMARY

EU procedure number	FR/V/0470/001-002/DC
Name, strength and pharmaceutical form	FIPRONIL PYRIPROXYFEN ALFAMED 50 MG/60 MG SPOT-ON SOLUTION FOR CATS FIPRONIL PYRIPROXYFEN ALFAMED 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	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 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. 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.

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).

SUMMARY OF ASSESSMENT

Legal basis of original application	Aplication 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.

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.