



Veterinary
Medicines
Directorate

**United Kingdom
Veterinary Medicines Directorate
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**MUTUAL RECOGNITION
PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

Frontline Plus Spot-on Cat

Date Created: December 2017

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0676/005
Name, strength and pharmaceutical form	Frontline Plus Spot-on Cat
Applicant	Boehringer Ingelheim Animal Health UK Limited Ellesfield Avenue Bracknell Berkshire RG12 8YS United Kingdom
Active substance(s)	Fipronil (S)-methoprene
ATC Vetcode	QP53AX65
Target species	Cats, ferrets
Indication for use	<p>In cats:</p> <ul style="list-style-type: none">- To be used against infestations with fleas, alone or in association with ticks and/or biting lice.- Elimination of fleas (<i>Ctenocephalides</i> spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for six weeks after application.- Elimination of ticks (<i>Ixodes ricinus</i>, <i>Dermacentor variabilis</i>, <i>Rhipicephalus sanguineus</i>). The product has a persistent acaricidal efficacy for up to 2 weeks against ticks (based on experimental data).- Elimination of biting lice (<i>Felicola subrostratus</i>). <p>In ferrets:</p> <ul style="list-style-type: none">- To be used against infestations with

	<p>fleas, alone or in association with ticks.</p> <ul style="list-style-type: none">- Elimination of fleas (<i>Ctenocephalides</i> spp.). Insecticidal efficacy against new infestations with adult fleas persists for 4 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity), larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas.- Elimination of ticks (<i>Ixodes ricinus</i>,). The product has a persistent acaricidal efficacy for 4 weeks against ticks (based on experimental data).
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MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed Consent application in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Date product first authorised in the Reference Member State (MRP only)	23 rd September 2015.
Concerned Member States for original procedure	UK (UK became Reference Member State on expiry of the authorisation in France in May 2016).

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Frontline Combo Spot-on Cat. The initial application for Frontline Combo Spot-on Cat was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

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.

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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.

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