United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

MUTUAL RECOGNITION
PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Frontline Plus Spot-on Dog S
Frontline Plus Spot-on Dog M
Frontline Plus Spot-on Dog L
Frontline Plus Spot-on Dog XL

Date Created: December 2017

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0676/001 UK/V/0676/002 UK/V/0676/003 UK/V/0676/004
Name, strength and pharmaceutical form	Frontline Plus Spot-on Dog S (Dogs 2-10 kg) Frontline Plus Spot-on Dog M (Dogs 10-20 kg) Frontline Plus Spot-on Dog L (Dogs 20-40 kg) Frontline Plus Spot-on Dog XL (ogs > 40 kg)
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	Dogs
Indication for use	- To be used against infestations with fleas, alone or in association with ticks and/or biting lice. - Treatment of flea infestations (*Ctenocephalides* spp.). Insecticidal efficacy against new infestations with adult fleas persist for 8 weeks. Prevention of the multiplication of fleas by inhibiting the development of eggs (ovicidal activity) and larvae and pupae (larvicidal activity) originating from eggs laid by adult fleas for eight weeks after application. - Treatment of tick infestations (*Ixodes ricinus*, *Dermacentor variabilis, Dermacentor reticulatus*, *Rhipicephalus sanguineus*) The

	product has a persistent acaricidal efficacy for up to 4 weeks against ticks. - Treatment of infestations with biting lice (*Trichodectes canis*).

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)	23rd 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 these products are identical to the Frontline Combo Spot-on Dog series. The initial applications for the Frontline Combo Spot-on Dog series were 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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