Veterinary Medicines Directorate

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

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Frontline Tri-Act Spot-on Solution for Dogs 10-20 kg
Frontline Tri-Act Spot-on for Dogs 20-40 kg
Frontline Tri-Act Spot-on for Dogs 2-5 kg
Frontline Tri-Act Spot-on for Dogs 40-60 kg
Frontline Tri-Act Spot-on for Dogs 5-10 kg

Date Created: February 2020

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Frontline Tri-Act Spot-on Solution for Dogs 10-20 kg Frontline Tri-Act Spot-on for Dogs 20-40 kg Frontline Tri-Act Spot-on for Dogs 2-5 kg Frontline Tri-Act Spot-on for Dogs 40-60 kg Frontline Tri-Act Spot-on for Dogs 5-10 kg
Applicant	Boehringer Ingelheim Animal Health UK Limited Ellesfield Avenue Bracknell Berkshire RG12 8YS United Kingdom
Active substance	Fipronil/Permethrin at various strengths: Frontline Tri-Act Spot-on Solution for Dogs 10-20 kg: 135.2 mg fipronil/1009/.6mg permethrin Frontline Tri-Act Spot-on for Dogs 20-40 kg: 270.4 mg fipronil/ 2019.2 mg permethrin Frontline Tri-Act Spot-on for Dogs 2-5 kg: 33.8 mg fipronil/252.4 mg permethrin Frontline Tri-Act Spot-on for Dogs 40-60 kg: 405.6 mg fipronil/ 3028.8 mg permethrin Frontline Tri-Act Spot-on for Dogs 5-10 kg: 67.6 mg fipronil/ 504.8 mg permethrin
ATC Vetcode	QP53AX65
Target species	Dogs
Indication for use	In dogs: For the treatment and prevention of flea (killing effect) and/or tick (killing and repellent effects) infestations where repellent activity is necessary against mosquitoes, sandflies and/or biting flies.

	• <u>Fleas</u> Treatment and prevention of *Ctenocephalides felis* flea infestations and prevention of *Ctenocephalides canis* flea infestations. One treatment prevents new flea infestations for 4 weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis where this has been previously diagnosed by a veterinarian. • <u>Ticks</u> Treatment and prevention of tick infestations (*Dermacentor reticulatus, Ixodes ricinus, Rhipicephalus sanguineus*). One treatment kills (*Dermacentor reticulatus, Ixodes ricinus, Rhipicephalus sanguineus*) and repels (*Ixodes ricinus, Rhipicephalus sanguineus)* ticks for 4 weeks after treatment, and repels *Dermacentor reticulatus* from 7 days up to 4 weeks after treatment. • <u>Mosquitoes and sandflies</u> Repels (anti-feeding activity) sandflies (*Phlebotomus perniciosus*) for 3 weeks and mosquitoes *(Culex pipiens, Aedes albopictus*) for 4 weeks. Kills sandflies (*Phlebotomus perniciosus)* and mosquitoes *(Aedes albopictus)* for 3 weeks. • <u>Biting flies (Stable flies)</u> Repels (anti-feeding activity) and kills stable flies (*Stomoxys calcitrans*) for 5 weeks.

MODULE 2

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

(www.gov.uk/check-animal-medicine-licensed)

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 of conclusion of the procedure	27th January 2020

I. SCIENTIFIC OVERVIEW

The quality/safety/efficacy aspects of these products are identical to the respective products in the Frontect Spot-on Solution for Dogs series.

II. OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the products are used in accordance with the Summary of Product Characteristics, the benefit/risk profile of the products 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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