FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
AGENCE NATIONALE DU MEDICAMENT VETERINAIRE
14 rue Claude Bourgelat –
Parc d'activités de la grande Marche –
Javené – CS 70611 –
35306 FOUGERES

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Fipronil/Permethrin Boehringer Ingelheim spot-on solution for dogs 2-5 kg
Fipronil/Permethrin Boehringer Ingelheim spot-on solution for dogs 5-10 kg
Fipronil/Permethrin Boehringer Ingelheim spot-on solution for dogs 10-20 kg
Fipronil/Permethrin Boehringer Ingelheim spot-on solution for dogs 20-40 kg
Fipronil/Permethrin Boehringer Ingelheim spot-on solution for dogs 40-60 kg

DATE : 2020.08.11.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0423/001-005/DC
Name, strength and pharmaceutical form	Fipronil/Permethrin Boehringer Ingelheim spot-on solution for dogs 2-5 kg Fipronil/Permethrin Boehringer Ingelheim spot-on solution for dogs 5-10 kg Fipronil/Permethrin Boehringer Ingelheim spot-on solution for dogs 10-20 kg Fipronil/Permethrin Boehringer Ingelheim spot-on solution for dogs 20-40 kg Fipronil/Permethrin Boehringer Ingelheim spot-on solution for dogs 40-60 kg
Applicant	Boehringer Ingelheim Animal Health France – 29 Avenue Tony Garnier – 69007 Lyon
Active substance(s)	Fipronil & Permethrin
ATC Vetcode	QP53AX65
Target species	Dogs
Indication for use	For the treatment and prevention of flea and/or tick infestations where repellent (anti-feeding) activity is necessary against sandflies, biting flies and/or mosquitoes. • Fleas 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. • Ticks 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>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 website https://www.anses.fr/en/thematique/veterinary-medicine-anmv

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of application	Informed consent application in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Date of completion of the application	13/05/2020
Concerned Member States	DK, FI, SE

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of these products are identical to “Frontline Tri-Act Spot-on Solution for dogs” products (reference products).

II. QUALITY ASPECTS

A. Composition

The product contains 6.760% (w/v) fipronil and 50.48% (w/v) permethrin as active substances and excipients butylhydroxytoluene, N-methylpyrrolidone and medium-chain triglycerides.

The packaging of the finished product is as described on the SPC. The particulars of the containers and controls performed are provided and conform to the regulation.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.
Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substances are permethrin and fipronil, established active substances.
The active substance specifications are considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

Not applicable.

F. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.
Satisfactory validation data for the analytical methods have been provided.
Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

G. Stability

Stability data on the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substances when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

See part IV.A

Toxicological Studies

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

User Safety

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, a user safety assessment is not required.

Environmental Risk Assessment

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, an environmental risk assessment is not required.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, pre-clinical studies are not required.

Tolerance in the Target Species of Animals

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, tolerance studies are not required.

IV.B Clinical Studies

As this is an informed consent application according to Article 13.c, and bioequivalence with a reference product has been demonstrated, clinical studies are not required.
The efficacy claims for this product are equivalent to those of the reference product.

V. 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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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 veterinary Heads of Agencies website (https://www.hma.eu/veterinarymedicines.html).

This section 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.

<None>