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

Fipmetho Combo 50 mg/60 mg Spot-on Solution for Cats
Katkin Flea & Tick 50 mg/60 mg Spot-on Solution for Cats
KRKA Combo 50 mg/60 mg Spot-on Solution for Cats
KRKA 50 mg/60 mg Spot-on Solution for Cats
RSPCA FLEAaway Combo 50 mg/60 mg Spot-on Solution for Cats

Date Created: October 2022

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Fipmetho Combo 50 mg/60 mg Spot-on Solution for Cats Katkin Flea & Tick 50 mg/60 mg Spot-on Solution for Cats KRKA Combo 50 mg/60 mg Spot-on Solution for Cats KRKA 50 mg/60 mg Spot-on Solution for Cats RSPCA FLEAaway Combo 50 mg/60 mg Spot-on Solution for Cats
Applicant	Krka d.d. Novo Mesto Šmarješka Cesta 6 8501 Novo Mesto Slovenia
Active substance	Fipronil S-methoprene
ATC Vetcode	QP53AX65
Target species	Cats
Indication for use	To be used against infestations with fleas, alone or in association with ticks and/or biting lice: • Treatment of fleas (*Ctenocephalides* 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. • Treatment of ticks (*Ixodes ricinus, Dermacentor variabilis, Rhipicephalus sanguineus*). The product has a persistent acaricidal efficacy for up to 2 weeks against ticks (based on experimental data). • Treatment of biting lice (*Felicola subrostratus*).

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	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	

I. SCIENTIFIC OVERVIEW

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

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains fipronil and S-methoprene and the excipients povidone K25, polysorbate 80, butylhydroxytoluene (E321), butylhydroxyanisole (E320), ethanol 96%, diethylene glycol monoethyl ether.

The container/closure system consists of a unit-dose pipette made of polypropylene and sealed with a membrane. The pipette is capped with a cap made of polyethylene or polyoxymethylene. Each pipette is packed in a laminated aluminium bag. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

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

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of adding ingredients and dissolving before mixing.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

II.C. Control of Starting Materials

The first active substance is fipronil, an established active substance described in the European Pharmacopoeia. The second active substance is S-methoprene which is described in in house monographs. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

All excipients are described in Ph. Eur. and all packaging complies.

II.C.4. Substances of Biological Origin

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

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.E. 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. Control tests on the finished product are those for: appearance, density, uniformity of dosage units, identification of fipronil, identification of S-methoprene, identification of butylhydroxyanisole, identification of butylhydroxytoluene, related substances of fipronil, related substances of S-methoprene, content of fipronil, content of S-methoprene, content of butylhydroxyanisole, content of butylhydroxytoluene and microbiological quality.

II.F. Stability

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.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

This veterinary medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from light and moisture.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Not required due to the legal basis of the application.

Toxicological Studies

Not required due to the legal basis of the application.

User Safety

A user risk assessment was provided in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore the following applicant's user recommendations are appropriate:

- This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided.
- People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with the product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.
- After accidental ocular exposure the eye should be rinsed carefully in clean water.
- If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the physician.
- Wash hands after use.
- Do not smoke, drink or eat during application.
- Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.
- Keep pipettes in original packaging until ready to use.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:
The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Pharmacology

Not required due to the legal basis of the application.

Tolerance in the Target Species

Not required due to the legal basis of the application.

IV.II. Clinical Documentation

Not required due to the legal basis of the application.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that the benefit/risk profile of the products are 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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