FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
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DECENTRALISED PROCEDURE (FORMERLY, UK AS RMS)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Canishield 0.77 g Medicated Collar for Small and Medium Sized Dogs

Canishield 1.04 g Medicated Collar for Large Sized Dogs

Merlin 1.04 g Medicated Collar for Large Sized Dogs

DATE: 28 March 2023

MODULE 1

PRODUCT SUMMARY

EU Procedure numbers	New product n° FR/V/0388/001 (old procedure number UK/V/0657/001/DC) New product n° FR/V/0387/001 (old procedure number UK/V/0606/001/DC) New product n° FR/V/0386/001 (old procedure number UK/V/0656/001/DC) Change of RMS: 15 October 2018
Name, strength and pharmaceutical form	Canishield 0.77 g Medicated Collar for Small and Medium Sized Dogs Canishield 1.04 g Medicated Collar for Large Sized Dogs Merlin 1.04 g Medicated Collar for Large Sized Dogs
Applicant	Beaphar B.V. Drostenkamp 3 8101 BX Raalte Netherlands
Active substance(s)	Deltamethrin
ATC Vetcode	QP53AC11
Target species	Dogs
Indication for use	The veterinary medicinal product provides: • Persistent flea (*Ctenocephalides felis*) killing activity for 16 weeks; • Persistent tick (*Ixodes ricinus*) killing activity for 6 months; • Sandfly (*Phlebotomus perniciosus*) anti-feeding and killing activity for 5.5 months.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original applications	Generic 'hybrid' applications in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedures	06 June 2018 National phase (FR): 26 June 2018
Concerned Member States for original procedures	Canishield 0.77 g Medicated Collar for Small and Medium Sized Dogs: Bulgaria, Croatia, Czech Republic, Finland, France, Germany, Hungary, Latvia, Lithuania, Netherlands, Norway, Poland, Romania, Slovakia and Slovenia. UK added via RMS change. BE, CY, EE, EL, ES, IE, IT, MT, PT added following repeat use procedure ended on 19 June 2019 (FR/V/0388/001/E/001) Canishield 1.04 g Medicated Collar for Large Sized Dogs: Belgium, Bulgaria, Croatia, Cyprus, Czech republic, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia and Spain. UK added via RMS change Merlin 1.04 g Medicated Collar for Large Sized Dogs: France, Italy, Portugal and Spain. UK added via RMS change
Concerned Member States for subsequent recognition procedure (SRP) FR/V/0387/001/E/001	Canishield 1.04 g Medicated Collar for Large Sized Dogs: Finland

I. SCIENTIFIC OVERVIEW

These applications were submitted in accordance with Article 13(3) of Directive 2001/82/EC, as amended by 2004/28/EC. The reference product is Scalibor

Protectorband 4% w/w 65 cm Collar for Large Sized Dogs, which has been authorised in the UK since 21st March 2002.

These were determined generic 'hybrid' applications because as the products are locally acting, *in vivo* bioequivalence cannot be demonstrated. An *in vitro* dissolution study and *in vivo* comparative release study, to demonstrate a comparable release profile of the proposed products compared to the reference product were provided. The products contain either 0.77 g or 1.04 g of deltamethrin, depending on for which size of dog the products are intended.

The products are produced and controlled using validated methods and tests which ensure the consistency of the product released onto the market. It has been shown that the products can be safely used in the target species, any reactions observed are indicated in the SPC.[1] The products are safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy [2] of the products was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The products are medicated collars for dogs containing Deltamethrin as the active substance, in a coloured, plastic base. The base is formed from the excipients; Stearic Acid, Triphenyl Phosphate, Calcium Stearate, epoxidized soybean oil, diisononyl adipate, zinc stearate, polyvinyl chloride, with carbon black as colouring.

Collars are packed in a multi-layered polyethylene terephthalate (PET)/polyethylene (PE)/aluminium (AI) foil/surlyn sachet. 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.

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.

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is Deltamethrin, an established active substance described in the British Veterinary Pharmacopoeia. 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.

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 substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance 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 DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological & Toxicological Studies

These applications are generic 'hybrid' products and were submitted in accordance with Article 13(3) of Directive 2001/82/EC, as amended, since bioequivalence cannot be demonstrated. The applications were submitted on the basis that the formulation is qualitatively the same as the reference product in regard to active substance and pharmaceutical form, pharmacological and toxicological studies were not required for these applications.

User Safety

A user risk assessment was provided in compliance with the relevant guideline. Dermal exposure through handling the collar and having contact with the treated animal and subsequent oral exposure through hand to mouth contact have been identified as likely routes of exposure. In addition, accidental oral exposure through a child chewing or sucking the collar has been considered as unlikely route of exposure. Deltamethrin and triphenyl phosphate (TPP) were identified as substances of possible concern and exposure calculations were considered for both.

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:

- Accidental ingestion of this product may cause adverse reactions, including neurotoxic effects.
- Keep the product in the original carton. Keep the collar in the sachet until use.
- Do not smoke, eat or drink while handling the collar.

- Do not allow children to play with the collar or to put it into their mouths. Immediately dispose of any remnants or cut-offs of the collar.
- Wash hands with cold water after fitting the collar.
- Avoid prolonged contact with the collar or dog wearing the collar. This includes sharing a bed with dogs wearing the collar; this is particularly important for children.
- In case of accidental oral exposure or ingestion, seek medical advice and show the package leaflet or the label to the doctor.

Deltamethrin may cause hypersensitivity (allergic) reactions in sensitive people. People with known hypersensitivity to Deltamethrin should avoid contact with the veterinary medicinal product and the treated animal. Seek medical advice in case of hypersensitivity reactions.

Environmental Safety

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

Phase I:
The applicant provided a Phase I ERA and has correctly shown that the assessment should conclude at question 3 of the decision tree, based on use in non-food producing animals only. However, since the products are ectoparasiticides for topical use, an additional risk mitigation measure has been added as follows: Deltamethrin is toxic for aquatic organisms. Dogs wearing the collar are not allowed to enter waterways.
The disposal advice also includes the wording: This product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

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.

III.B Residues documentation
The product is only indicated for use in non-food species (dogs) and as such there are no consumer safety issues to address.

IV CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Since the application is made in accordance with Article 13(3) of Directive 2004/28/EC, on the basis of essential similarity, data on this section of the dossier were not provided.

The applicant has submitted an in vitro dissolution study and an in vivo release comparison study, which both demonstrate the release of deltamethrin from the proposed collar is equivalent to the one of the reference collar.

Tolerance in the Target Species

Since the application is made in accordance with Article 13(3) of Directive 2004/28/EC, on the basis of essential similarity, target animal safety studies were not required. Local tolerance was provided by five dose confirmation studies and one clinical field study. The applicant submitted literature to support safety of excipients and the active substance. An *in vitro* dissolution study and *in vivo* comparative release study, to demonstrate a comparable release profile of the proposed products compared to the reference product was also provided.

IV.I. Clinical Studies

Five dose confirmation studies and one clinical field study were provided to support the indications for use.

V 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 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.

Quality changes

Summary of change **(Application number)**	**Section updated in Module 3**	**Approval date**
Change to specification of an excipient, change to the finished product specification (FR/V/xxxx/WS/053)	N/A	26/08/2020

Other

Summary of change **(Type; application number)**	**Section updated in Module 3**	**Approval date**
Update the product information in line with QRD version 9.0. (FR/V/xxxx/A/177/G)	N/A	22/12/2022