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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

PREVENDOG 0.636 g medicated collar for very small dogs
PREVENDOG 1.056 g medicated collar for small to medium dogs
PREVENDOG 1.304 g medicated collar for large to very large dogs

DATE: 27/02/2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0328/001-003/DC
Name, strength and pharmaceutical form	PREVENDOG 0.636 g medicated collar for very small dogs PREVENDOG 1.056 g medicated collar for small to medium dogs PREVENDOG 1.304 g medicated collar for large to very large dogs
Applicant	VETPHARMA ANIMAL HEALTH, S.L. Les Corts, 23 08028 - Barcelona Spain
Active substance(s)	Delthametrin
ATC Vetcode	QP53AC11.
Target species	Dogs
Indication for use	Deltamethrin-sensitive parasite infestations. Prevention of tick re-infestation (*Ixodes ricinus* and *Rhipicephalus sanguineus*) through an acaricidal effect for 6 months. Prevention of sandfly bites (*Phlebotomus perniciosus*) due to repellent (anti-feeding) effect for 5 months. Prevention of mosquito bites (*Culex pipiens*) due to repellent (anti-feeding) effect for 6 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 application	Generic 'hybrid' application in accordance with Article 13 (3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	19/12/2018
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, EL, ES, HU, IE, IT, LU, NL, PL, PT, RO, SK,

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 COLLIER PETIT CHIEN ET CHIEN MOYEN, marketed by INTERVET, which has been authorized in France since 05/03/1997.

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 were provided to demonstrate a comparable release profile of the proposed products to the reference product.

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

II. QUALITY ASPECTS

A. Composition

The product contains 40 mg/g of deltamethrin as active substance and the excipients polyvinyl chloride, calcium stearate, soybean oil, epoxidized, diisooctyl adipate, titanium dioxide, triphenyl phosphate and calcium zinc stearates.
One collar of 35 cm (15.90 g) contains 0.636 g of deltamethrin.
One collar of 60 cm (26.40 g) contains 1.056 g of deltamethrin.
One collar of 75 cm (32.60 g) contains 1.304 g of deltamethrin.

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 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

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

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 ASSESSMENT

III.A Safety Testing

Pharmacological Studies &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 and quantitatively similar to the reference product in regard to active substance, excipients and pharmaceutical form, hence pharmacological and toxicological studies were not required for these applications.

User Safety

The applicant has provided a user safety assessment 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:

Accidental ingestion of this product may cause adverse effects, 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. Keep away from food, drink and animal feeding stuffs.

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.

In case of accidental oral exposure or ingestion, seek medical advice and show the package leaflet or the label to the doctor.

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.

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 Risk Assessment

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals and as a result environmental exposure will be low.

However, since the products are ectoparasiticides for topical use, an additional risk mitigation measure has been added as follows: Deltamethrin is toxic for the fish and other aquatic organisms. Dogs wearing the collar should not be allowed to swim in the water courses..

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.

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 ASSESSMENT (EFFICACY)

IV.A 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 of Animals

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. 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 type and incidence of adverse effects presented in the product literature are equivalent as that of the SPC of the reference product.

IV.B Clinical Studies (pharmaceuticals and immunologicals)

No clinical studies were provided on the basis of essential similarity. Moreover, the applicant provided an in vitro dissolution study and an in-vivo diffusion study between candidate and reference products which support the claim for essential similarity between candidate and reference products in accordance with guideline requirements.
As such the target animal safety and efficacy are the same that of the reference product SCALIBOR COLLIER.

The following indications for use in dogs were accepted:

“Deltamethrin-sensitive parasite infestations.

Prevention of tick re-infestation (*Ixodes ricinus* and *Rhipicephalus sanguineus*) through an acaricidal effect for 6 months.
Prevention of sandfly bites (*Phlebotomus perniciosus*) due to repellent (anti-feeding) effect for 5 months.
Prevention of mosquito bites (*Culex pipiens*) due to repellent (anti-feeding) effect for 6 months."

As the collar exerts its full effect after one week, the collar should be preferably applied 1 week before animals are likely to become exposed to the above-mentioned infestations.
Ticks would be killed and fall off the host within 24 to 48 hours after infestation without having had a blood meal, but an attachment of single ticks after treatment cannot be excluded. Thus, a transmission of infectious diseases by ticks cannot be excluded. Under unfavourable conditions, the transmission of infectious diseases through sandflies cannot be ruled out entirely.

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.