AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

Agence nationale du médicament vétérinaire (ANMV)
French agency for veterinary medicinal products

AGENCE NATIONALE DE SÉCURITÉ SANITAIRE de l'alimentation, de l'environnement et du travail
FRENCH AGENCY FOR FOOD, ENVIRONMENTAL AND OCCUPATIONAL HEALTH AND SAFETY
14 rue Claude Bourgelat – PA de la Grande Marche – Javené - CS 70611 – F-35306 FOUGERES Cedex
www.anses.fr — @Anses_fr

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

VETOCANIS Collar 0.77 g Deltamethrin for Small and Medium Sized Dogs

VETOCANIS Collar 1.04 g Deltamethrin for Large Sized Dogs

PRODUCT SUMMARY

EU procedure number	FR/V/0463/001-002/DC
Name, strength and pharmaceutical form	VETOCANIS Collar 0.77 g Deltamethrin for Small and Medium Sized Dogs VETOCANIS Collar 1.04 g Deltamethrin for Large Sized Dogs
Applicant	Beaphar B.V.
Active substance(s)	Deltamethrin
ATC vetcode	QP53AC11
Target species	Dogs
Indication for use	The veterinary medicinal product provides: • Prevention of fleas re-infestation with Ctenocephalides felis through an insecticidal effect for 16 weeks; • Prevention of tick re-infestation with Ixodes ricinus through an acaricidal effect for 6 months; • Prevention of bites by sandflies (Phlebotomus perniciosus) through an insecticidal and anti-feeding effect for 5.5 months.

VETOCANIS Collar 0.77 g Deltamethrin for Small and Medium Sized Dogs VETOCANIS Collar 1.04 g Deltamethrin for Large Sized Dogs	FR/V/0463/001-002/DC
Beaphar B.V.	DCP
Publicly available assessment report	

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

VETOCANIS Collar 0.77 g Deltamethrin for Small and Medium Sized Dogs VETOCANIS Collar 1.04 g Deltamethrin for Large Sized Dogs	FR/V/0463/001-002/DC
Beaphar B.V.	DCP
Publicly available assessment report	

SUMMARY OF ASSESSMENT

Legal basis of original application	Hybrid application in accordance with Article 19 (1) of Regulation (EU) 2019/6
Date of completion of the original decentralised>procedure	10/03/2023
Concerned Member States for original procedure	ES, PT

1. SCIENTIFIC OVERVIEW

The veterinary medicinal products (VMP) VETOCANIS Collar 0.77 g Deltamethrin for Small and Medium Sized Dogs and VETOCANIS Collar 1.04 g Deltamethrin for Large Sized Dogs are produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMPs can be safely used in the target species; the adverse events observed are indicated in the SPC.

The VMPs are 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 VMPs was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMPs contain 4%w/w deltamethrin as the active substance in a coloured plastic base. The excipients of this base are stearic acid, triphenyl phosphate, calcium stearate, soybean oil epoxidized, diisononyl adipate, zinc stearate, polyvinyl chloride and carbon black.

The container/closure system is a multi-layered polyethylene terephthalate-polyethylene-aluminium foil-surlyn sachet.

The choice of the formulation is justified.

The VMPs are an established pharmaceutical form and their development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

The VMPs are manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

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

C. Production and control of starting materials

The active substance is deltamethrin, an established active substance described in the pharmacopeia of a third country. 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.

Scientific data 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.

D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable.

E. Control tests on the finished product

The finished product specifications control the relevant parameters for the pharmaceutical form. The tests in the specifications and their limits have been justified and are considered appropriate to adequately control the quality of the VMP.

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.

F. Stability tests

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 VMP throughout its shelf life when stored under the approved conditions.

VETOCANIS Collar 0.77 g Deltamethrin for Small and Medium Sized Dogs VETOCANIS Collar 1.04 g Deltamethrin for Large Sized Dogs	FR/V/0463/001-002/DC
Beaphar B.V.	DCP
Publicly available assessment report	

3. SAFETY DOCUMENTATION (safety and residues tests)

A. Safety tests

Pharmacological and Toxicological studies

These applications are 'hybrid' products and were submitted in accordance with Article 19 (1) of Regulation (EU) 2019/6 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. 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 VMP. 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 immediately and show the package leaflet or the label to the physician.

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

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP will only be used in non-food animals.

However, additional concerns have been identified associated with the activity of the substance being an ectoparasiticide for topical use and a warning has been included in the section 3.5 Special precautions for the protection of the environment of the SPC.

VETOCANIS Collar 0.77 g Deltamethrin for Small and Medium Sized Dogs VETOCANIS Collar 1.04 g Deltamethrin for Large Sized Dogs	FR/V/0463/001-002/DC
Beaphar B.V.	DCP
Publicly available assessment report	

B. Residues documentation

Not applicable, as the test products are intended for non-food producing species.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

The products are deltamethrin impregnated collars for dogs containing deltamethrin.

The applications have been submitted in accordance with Article 19 (1) of Regulation (EU) 2019/6 as the products are locally acting and *in vivo* bioequivalence cannot be demonstrated. The reference products are Scalibor Protectorband 4% w/w 48 cm Halsband fur kleine und mittelere Hunde and Scalibor Protectorband 4% w/w 65 cm, authorised in Germany in 1999 and approved in other member states *via* the mutual recognition procedure.
As these are hybrid applications according to Article 19 of Regulation (EU) 2019/6 and bioequivalence with a reference VMP has not been demonstrated, data to support efficacy have been evaluated.

A. Pre-Clinical Studies

Since the application is made in accordance with Article 19 of Regulation2019/6 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.

Development of resistance and related risk in animals

The applicant provided an updated literature review to give an overview of the state of resistance in the target parasites to deltamethrin.

Tolerance in the target species of animals

Since the applications are made in accordance with Article 19 (1) of Regulation 2019/6 (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.

The adverse events and overdose information listed in section 3.6 and 3.10 of the SPC of the proposed product reflect that of the reference product and are satisfactory.

B. Clinical trials

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

The efficacy claims for these VMPs are similar to those of the references VMPs. However, the wording has been updated to be in line with requirements of the current guideline for the testing

VETOCANIS Collar 0.77 g Deltamethrin for Small and Medium Sized Dogs VETOCANIS Collar 1.04 g Deltamethrin for Large Sized Dogs	FR/V/0463/001-002/DC
Beaphar B.V.	DCP
Publicly available assessment report	

and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in dogs and cats - EMEA/CVMP/EWP/005/2000-Rev. 4.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossiers demonstrate that when the VMPs are 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 VMPs for humans and the environment is acceptable.