Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Milbeguard Duo 12.5 mg/125 mg Chewable Tablets for Dogs
Milbeguard Duo 2.5 mg/25 mg Chewable Tablets for Small Dogs and Puppies
Milbeguard Duo 25 mg/250 mg Chewable Tablets for Large Dogs

Date Created: January 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Milbeguard 2.5 mg/25 mg Chewable Tablets for Small Dogs and Puppies Milbeguard 12.5 mg/125 mg Chewable Tablets for Dogs Milbeguard 25 mg/250 mg Chewable Tablets for Large Dogs
Applicant	Ceva Animal Health Ltd Unit 3 Anglo Office Park White Lion Road Amersham Buckinghamshire HP7 9FB
Active substance	Milbemycin Oxime (A3 and A4) Praziquantel
ATC Vetcode	QP54AB51
Target species	Dogs
Indication for use	In dogs: treatment of mixed infections by adult cestodes and nematodes of the following species: • Cestodes: *Dipylidium caninum* *Taenia* spp. *Echinococcus* spp. *Mesocestoides* spp. • Nematodes: *Ancylostoma caninum* *Toxocara canis* *Toxascaris leonina* *Trichuris vulpis* *Crenosoma vulpis* (Reduction of the level of infection) *Angiostrongylus vasorum* (Reduction of the level of infection by immature adult (L5) and adult parasite stages.) *Thelazia callipaeda*

	The product can also be used in the prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes is indicated.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Two generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended: Milbeguard Duo 2.5 mg / 25 mg Milbeguard Duo 12.5 mg /125 mg And one hybrid application in accordance with Article 13(3) of Directive 2001/82/EC as amended: Milbeguard Duo 25 mg / 250 mg
Date of conclusion of the procedure	2/11/23

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Milbemax. The initial application for Milbemax 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 milbemycin oxime and praziquantel and the excipients povidone, croscarmellose sodium, lactose monohydrate, artificial chicken flavour, yeast, cellulose microcrystalline, silica colloidal anhydrous, magnesium stearate.

The container/closure system consists of a polyamide/aluminium/polyvinyl chloride blister sealed with aluminium foil. 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: weighing, sieving, mixing, wetting, granulation, and drying.

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

II.C. Control of Starting Materials

The active substances are milbemycin oxime and praziquantel, which are established active substances described in the European Pharmacopoeia. The active substances are 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, except for chicken flavour and yeast, are described in Ph. Eur.

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, milbemycin oxime and praziquantel identification, thickness, friability, hardness, uniformity of mass, subdivision of tablets (into halves), water content, disintegration, dissolution, assays of the active substances, relative substances and microbial contamination.

II.F. Stability

Stability data on the active substances 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.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life for halved tablet after first opening the blister: 6 months
Any unused tablet parts should be returned to the opened blister, inserted back into the outer packaging and used at the next administration or securely discarded.
Protect from light.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Not provided due to the legal basis of the application. Bioequivalence was established in studies.

Toxicological Studies

Not required.

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 veterinary medicinal product may be harmful when ingested, particularly for children. To avoid accidental ingestion, the product should be stored out of sight and reach of children. Any unused part of tablet should be stored in the opened blister, inside the outer packaging and always be used at the next administration.
- In case of accidental ingestion of the tablets, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the physician.
- The product may cause a weak skin sensitization. Do not handle this product in case of known hypersensitivity to the active substances or to any of the excipients.

- Wash hands after 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; however a bioequivalence study was conducted.

Tolerance in the Target Species

Tolerance studies were not required; however, a target animal safety study was conducted.

IV.II. Clinical Documentation

Not required; however, a palatability field trial was conducted.

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.

(www.gov.uk/check-animal-medicine-licensed)

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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