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 16 mg / 40 mg Film-coated Tablets for Cats
Milbeguard Duo 4 mg / 10 mg Film Coated Tablets for Small Cats and Kittens

Date Created: January 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Milbeguard Duo 16 mg / 40 mg Film-coated Tablets for Cats Milbeguard Duo 4 mg / 10 mg Film Coated Tablets for Small Cats and Kittens
Applicant	Ceva Animal Health Ltd Explorer House Mercury Park Wycombe Lane Wooburn Green High Wycombe HP10 0HH
Active substance	Milbemycin Oxime (A3 and A4) Praziquantel
ATC Vetcode	QP54AB51
Target species	Cats
Indication for use	In cats: treatment of mixed infections by immature and adult cestodes and nematodes of the following species: • Cestodes: o *Dipylidium caninum* o *Taenia* spp. o *Echinococcus multilocularis* • Nematodes: o *Ancylostoma tubaeforme* o *Toxocara cati* 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	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	2/11/2023

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Milbemax Film-coated Tablets for Cats and Milbemax Film-coated Tablets for Small Cats and Kittens. 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

Milbeguard Duo 4 mg / 10 mg Film Coated Tablets for Small Cats and Kittens:
The product contains milbemycin oxime and praziquantel and the excipients povidone, croscarmellose sodium, artificial smoked chicken flavour, lactose monohydrate, cellulose microcrystalline, silica colloidal anhydrous, magnesium stearate, polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E15121), talc (E553b), iron oxide yellow (E172).

Milbeguard Dup 16 mg / 40 mg Film-Coated Tablets for Cats
The product contains milbemycin oxime and praziquantel and the excipients povidone, croscarmellose sodium, artificial smoked chicken flavour, lactose monohydrate, cellulose microcrystalline, silica colloidal anhydrous, magnesium stearate, polyvinyl alcohol (E1203), macrogol (E15121), talc (E553b), Ponceau 4R (E124), Sunset yellow (E110) and titanium dioxide (E171).

The container/closure system consists of PVC blister sealed with aluminium foil in an outer carton. 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: granulation and blending.

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. These are established active substances described in the European 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.

All excipients, with the exception of smoked chicken flavour and coating agent, 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, identifications, assays, microbial contamination, mass, water content, disintegration, dissolution, uniformity of dosage units, subdivision of tablets (into halves), harness and related substances.

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 required due to the legal basis of the application. Bioequivalence was claimed by a dissolution study and an *in vivo* bioequivalence study.

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 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 the event 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.
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. A bioequivalence study was conducted.

Tolerance in the Target Species

Tolerance studies were not required because bioequivalence was established.

IV.II. Clinical Documentation

Not required.

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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