Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Milpro Chewy 2.5 mg / 25.0 mg Chewable Tablets for Small Dogs and Puppies
Milpro Chewy 12.5 mg / 125.0 mg Chewable Tablets for Dogs
Milpro Chewy 25.0 mg / 250.0 mg Chewable Tablets for Large Dogs

Date Created: October 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Milpro Chewy 2.5 mg / 25.0 mg Chewable Tablets for Small Dogs and Puppies Milpro Chewy 12.5 mg / 125.0 mg Chewable Tablets for Dogs Milpro Chewy 25.0 mg / 250.0 mg Chewable Tablets for Large Dogs
Applicant	VIRBAC 1ère avenue 2065m LID 06516 Carros France
Active substance	Milbemycin oxime 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* *Angiostrongylus vasorum* (Reduction of the level of infection by immature adult (L5) and adult parasite stages) (see specific treatment and prevention disease schedules under section 4.9 “Amounts to be administered and administration route”)

	Thelazia callipaeda (see specific treatment schedule under section 4.9 “Amounts to be administered and administration route”) 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	Generic application in accordance with Article 8 of VMRs 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	17/7/24

I. SCIENTIFIC OVERVIEW

This application is for generic products with the reference products being Milbemax Chewable Tablets.

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, any reactions observed are indicated in the SPC.[1] 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 [2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains milbemycin oxime and praziquantel and the excipients meat flavour, maize starch, croscarmellose sodium, microcrystalline cellulose, confectioner's sugar, sodium chloride, ferric oxide, butylhydroxyanisole, macrogols 3350, glycerol, refined soya-bean oil and purified water.

The container/closure system consists of aluminium blisters in a cardboard box. 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.

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

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.

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

II.C. Control of Starting Materials

The active substances are milbemycin oxime and praziquantel which are established active substance 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 comply with Ph. Eur or USP except for veggie flavour which CoAs are provided.

II.C.4. Substances of Biological Origin

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.

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 suitable for this formulation.

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: 21 months.
Do not store above 25°C.
Store in the original package to 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.

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 cause hypersensitivity reactions. People with known hypersensitivity to butylhydroxyanisole, macrogols or soya (bean) oil should avoid contact with the veterinary medicinal product. If contact occurs, wash hands and seek medical advice in case of hypersensitivity reactions.
This veterinary medicinal product may be harmful after accidental ingestion. To avoid accidental ingestion, particularly by a child, blister cards should be inserted back into the carton and kept out of sight and reach of children. In case of accidental ingestion of the tablets, 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

The applicant has provided bibliographical information describing the pharmacodynamic and pharmacokinetic properties of the active substance. Bioequivalence was established with regards to the reference product.

Tolerance in the Target Species

Tolerance studies were not required because of the legal basis of the application.

IV.II. Clinical Documentation

Not required due to the legal basis of the application.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that 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 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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