Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Lemicam 1 mg Chewable Tablets for Dogs
Lemicam 2.5 mg Chewable Tablets for Dogs

Date Created: November 2022

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Lemicam 1 mg Chewable Tablets for Dogs Lemicam 2.5 mg Chewable Tablets for Dogs
Applicant	Felix Pharmaceuticals PVT Limited, 25-28 North Wall Quay, Dublin 1, D01H104, Ireland
Active substance	Meloxicam
ATC Vetcode	QM01AC06
Target species	Dogs
Indication for use	Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

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 applications in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	16/08/2022

I. SCIENTIFIC OVERVIEW

The products are chewable tablets containing 1 mg and 2.5 mg meloxicam respectively and are indicated for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.
The reference products are Metacam 1 mg Chewable Tablets for Dogs and Metacam 2.5 mg Chewable Tablets for Dogs, marketed by Boehringer Ingelheim Vetmedica GmbH, which have been authorised in the UK/GB since 23 March 2006.
The products are 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 products can be safely used in the target species, any reactions observed are indicated in the SPC.[1] The products are 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 products 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 the active substance meloxicam and the excipients microcrystalline cellulose, sodium citrate, maize starch pregelatinised, iron oxide brown, iron oxide yellow, artificial powdered flavour, silica colloidal anhydrous and magnesium stearate.

The container/closure system consists of a aluminium/aluminium foil blister pack. The tablets are circular with a score line on both sides and other identification marks. The finished packages are cardboard boxes containing 1, 12 or 36 strips of 7 tablets. The particulars of the containers and controls performed are provided and conform to the regulation.

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

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 of the active substance and excipients followed by blending with additional excipients and compression.

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

II.C. Control of Starting Materials

The active substance is meloxicam, an 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.

The meloxicam is supplied with a valid certificate of suitability.

The excipients which appear in the European Pharmacopoeia are required to comply with the current version of their respective monographs and include tests for functionality-related characteristics where appropriate. The specifications provided for the excipients not appearing in the European Pharmacopoeia are also satisfactory.

The blister packaging materials are described in detail and include confirmation of food contact approval.

II.C.4. Substances of Biological Origin

Satisfactory TSE information has been provided for the excipients, the active substance and the packaging materials.

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 Description, Identification, Friability, Hardness, Water content, Dissolution, Assay, Uniformity of dosage unit, Organic impurities and Microbial Enumeration tests.

II.F. 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.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies and Toxicological Studies

Due to the legal basis of the applications and the fact that the products have the same pharmaceutical form, contain the same active substance in the same quantities, and have the same excipients (excluding flavouring) in similar quantities as the reference products, no pharmacological or toxicological data have been submitted, with the exception of establishing bioequivalence.

A bioequivalence study was conducted on the 2.5 mg tablets, comparing their product to the equivalent strength of reference product (Metacam 2.5 mg Chewable Tablets for Dogs). The study was conducted to GLP standards using a fully validated LC-MS/MS method. The 90% confidence intervals for the ratios (test: reference) of the geometric means for the key parameters AUC_t and C_{max} fell within the acceptance limits of 80 - 125% required by the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.3-corr.). It was concluded that bioequivalence between the 2.5 mg test and reference products had been demonstrated. A waiver was provided for the requirement for bioequivalence studies in the 1 mg tablet product and was later granted.

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:,

- People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the product.
- Accidental ingestion of the product by a child may cause gastro-intestinal effects, such as nausea and gastric pain.
- Any uneaten medicated food must be disposed of immediately and the bowl washed thoroughly.
- Return part-used tablets into the blister and carton.
- In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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 proposed products, Lemicam 1 mg chewable tablets for dogs and Lemicam 2.5 mg chewable tablets for dogs, contain the same quantity of meloxicam as their respective reference products and are presented in the same pharmaceutical form. According to Article 13(1), they can be considered generics of the reference products if bioequivalence between the products is demonstrated. As bioequivalence had been demonstrated, no additional target species safety or efficacy data were required.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the products are used in accordance with the Summary of Product Characteristics 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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