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

Meloxyl 0.5 mg/ml Oral Suspension for Cats

Date Created: June 2022

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Meloxyl 0.5 mg/ml Oral Suspension for Cats
Applicant	EU Pharmaceuticals Ltd 37 Geraldine Road London SW18 2NR
Active substance	Meloxicam
ATC Vetcode	QM01AC06
Target species	Cats
Indication for use	Cats: Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery. Alleviation of pain and inflammation in acute and chronic musculoskeletal disorders in cats.

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	5/5/2022

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Metacam Oral Suspension 0.5 mg/ml. The initial application for Metacam 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 mexolicam and the excipients glycerol, citric acid monohydrate, xanthan gum, povidone, sodium dihydrogen phosphate monohydrate, sodium benzoate, simethicone emulsion, honey flavour, silica colloidal anhydrous and purified water.

The container/closure system consists of high-density polyethylene (HDPE) bottles with a tamperproof child resistant HDPE closure. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence 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 adding ingredients and mixing before leaving to settle.

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.

All excipients, except honey flavour, are subject of monographs in the Ph. Eur. or the United States Pharmacopoeia (USP).

Full details of the active are included in the ASMF and packaging is in accordance with the CEP.

II.C.4. Substances of Biological Origin

Declarations are provided from each of the suppliers of active substance and excipients confirming the absence of ingredients of animal origin.

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, identification, resuspendability test, pH, viscosity, assay active, assay preservative, particle size analysis, microbiology and uniformity of fill.

II.F. Stability

The active substance is fully tested to ensure compliance with its specification immediately prior to its use in manufacture of the product.

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: 36 months
Shelf life after first opening the immediate packaging:
3 ml and 5 ml bottle:14 days
10 ml and 15 ml bottle: 6 months

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Not required as this application is for a generic product.

Toxicological Studies

Not required as this application is for a generic product.

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 veterinary medicinal product.
- In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

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

No data for pharmacodynamics have been present as this is a generic application. The applicant has conducted an *in vivo* bioequivalence study describing the pharmacokinetic properties of the active substance. This showed bioequivalence to the reference product.

IV.II. Clinical Documentation

Not necessary as bioequivalence has been demonstrated.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that the benefit/risk profile of the product 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.

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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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