Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Rheumoxidyl 1.5 mg/ml Oral Suspension for Dogs

Date Created: July 2022

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Rheumoxidyl 1.5 mg/ml Oral Suspension for Cats
Applicant	EU Pharmaceuticals Ltd 37 Geraldine Road London SW18 2NR
Active substance	Meloxicam
ATC Vetcode	QM01AC06
Target species	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 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 1.5 mg/ml Oral Suspension for Dogs which has been authorised in the UK since 2000.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains meloxicam and the excipients sodium benzoate, citric acid monohydrate, disodium hydrogen phosphate dodecahydrate, honey flavour, colloidal silicon dioxide, saccharin sodium, sodium carboxyl methyl cellulose, and sorbitol solution.

The container/closure system consists of a polyethylene terephthalate (PET) or high-density polyethylene HDPE bottle with a tamper proof child-resistant 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 manufacturing of the bulk, colloid milling of the bulk and filling.

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.

One supplier of meloxicam refers to an ASMF and the other a Certificate of Suitability.

All excipients are compliant with either Ph. Eur. or USP standards.

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 sites have been provided demonstrating compliance with the specification. Control tests on the finished product are those for: appearance, identification of meloxicam, assay active, identification of preservative, assay preservative, pH, viscosity, microbial purity, uniformity of mass and particle size.

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.
Shelf life after first opening the immediate packaging: 6 months.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

In accordance with the legal status of the application, no pharmacodynamic studies are required, and none have been provided. The applicant has provided a pharmacokinetic study in cats to establish bioequivalence with the reference product. Bioequivalence was established so no additional studies are required.

Toxicological Studies

In accordance with the legal status of the application, no toxicological studies are required, and none have been provided.

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.
- Any uneaten medical food must be disposed of immediately and the bowl washed thoroughly.
- Do not leave an unattended filled syringe in the sight or reach of children.

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

Pharmacokinetics

The applicant has provided an *in* vivo bioequivalence study in cats comparing the proposed product and the reference product. Bioequivalence has been established.

Tolerance in the Target Species

Tolerance studies were not required.

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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