Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Pyrocam 15 mg/ml Oral Suspension for Pigs

Date Created: March 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Pyrocam 15 mg/ml Oral Suspension for Pigs
Applicant	Huvepharma N.V. Uitbreidingstraat 80 Antwerp, B-2600 Belgium
Active substance	Meloxicam
ATC Vetcode	QM01AC06
Target species	Pigs
Indication for use	For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation. For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (Mastitis-Metritis- Agalactia syndrome MMA) with appropriate antibiotic therapy.

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 hybrid application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	02/01/2024

I. SCIENTIFIC OVERVIEW

This was determined a generic 'hybrid' application because bioequivalence was only established in relation to AUC. Additional data was submitted. The reference product is Metacam 15 mg/ml oral suspension for pigs which has been authorised in GB since 2010.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains meloxicam and the excipients vanillin, microcrystalline cellulose, carmellose sodium, citric acid, sodium hydroxide, polysorbate 80 and water, purified.

The container/closure system consists of child resistant packaging consisting of an HDPE bottle closed with a polypropylene cap. 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: dissolving and stirring.

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 and packaging comply with the relevant monographs.

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: viscosity, resuspendability, appearance, identification, pH, related substances and microbial contamination.

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.

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: 2 years.
Shelf life after first opening the immediate packaging: 1 month.
Do not freeze.

Protect from frost.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Studies have been conducted regarding the pharmacological aspects of the active substance. The applicant has also provided bibliographical data, bioequivalence was established in relation to AUC.

Toxicological Studies

The applicant has provided data on the active substance despite the data not being required. The data showed that the product is unlikely to be toxic.

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 (allergic reactions).
- People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) or parabens should avoid contact with the veterinary medicinal product.
- This veterinary medicinal product can cause eye irritation. Personal protective equipment consisting of eye protection should be worn when handling the veterinary medicinal product. In case of contact with the eyes, immediately rinse thoroughly with water.
- Avoid oral exposure, including hand-to-mouth contact. Wash hands after use. Do not eat, drink or smoke while handling the veterinary medicinal product.
- In case of accidental ingestion,
  seek medical advice immediately and show the package leaflet or the label to the physician.
- Meloxicam may have adverse effects on pregnancy and/or embryofoetal development. Avoid dermal exposure including hand-to-mouth contact. Pregnant women or women attempting to conceive should wear impermeable gloves when administering the veterinary medicinal product.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:
The initial predicted environmental concentration (PEC) in soil is less than 100 µg/kg. A Phase II ERA was not required.

III.B.2 Residues documentation

Residue Studies

The applicant has conducted residue depletion studies using radiolabelled meloxicam which show that meloxicam was excreted in both urine and faeces and is extensively metabolised.

MRLs

Meloxicam is listed in Table 1 of Regulation 37/2010 and MRLs have been established.

MRLs are listed below:

	Bovine, caprine, procine, rabbit, Equidae
Muscle	20 µl/kg
Liver	65 µl/kg
Kidney	65 µl/kg

Withdrawal Periods

Based on the data provided, a withdrawal period of 5 days for meat in pigs are justified.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Pharmacology

The applicant has conducted studies describing the pharmacodynamic and pharmacokinetic properties of the active substance. A bioequivalence study was conducted and demonstrated in terms of AUC.

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 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.

(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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