Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Meloxyl 1.5 mg/ml Oral Suspension for Dogs

Date Created: July 2018

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Meloxyl 1.5 mg/ml Oral Suspension for Dogs
Applicant	EU Generics Limited 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 31(1) of Directive 2001/82/EC as amended by 2004/28/EC.
Date of conclusion of the procedure	28/06/2018

I. SCIENTIFIC OVERVIEW

This was an application for a generic product, submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended by 2004/28/EC. The reference product is Metacam 1.5 mg/ml Oral Suspension for Dogs, marketed in the UK since March 2000.

The product is indicated for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

The dosage is for an initial single treatment of 0.2 mg meloxicam/kg body weight, given orally. The treatment is then continued at a maintenance dose of 0.1mg meloxicam/kg body weight at 24 hour intervals. Once clinical response has been observed, the dose can be adjusted to the lowest effective individual dose. For the first day, twice the maintenance volume will be required.
A clinical response is normally seen within 3–4 days. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

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 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.

[1] SPC – Summary of Product Characteristics.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

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

The container system consists of 42, 100 or 200ml polyethylene terephthalate (PET) bottle with a tamper resistant child proof closure and a 15ml HDPE bottle with a tamper resistant child proof closure, and two polypropylene measuring syringes. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of a 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: primarily mixing of the bulk product before colloid milling, then filling into the bottle.

II.C. Control of Starting Materials

The active substance is Meloxicam, an established active substance described in the European Pharmacopoeia (Ph.Eur). 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 are controlled in accordance with the relevant Ph. Eur. monographs with the exception of honey flavour, which is tested according to the supplier's specifications. The relevant certificates of analysis and a copy of the in-house tests and specifications have been provided for the honey flavour.

The active substance is packaged in double layer polyethylene bags, which are sealed with a self-locking ribbon, then stored in fibre drums, which are sealed with a plastic safety seal.

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. It is noted that one of the components of the packaging may contain tallow derived additives.

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 include those for: appearance, identification of meloxicam, assay active, pH, identification of preservative, assay preservative, particle size analysis, viscosity, microbiological quality and uniformity of mass of delivered dose.

II.F. Stability

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. The retest period is 5 years when packaged in fibre drums with inner double layer polyethylene bags. 5 years for active substance, 2 years for finished product

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.
This veterinary medicinal product does not require any special storage conditions.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Pharmacodynamics

The product has the same qualitative profile and the same quantitative amount of the active substance and is used in the same way as the reference product. In order to assure bioequivalence between the proposed product and the reference product a suitable study was submitted.

Pharmacokinetics

A suitable pharmacokinetic study was performed in order to assure bioequivalence between the proposed product and the reference product.

Toxicological Studies

A user risk assessment (URA) was submitted in accordance with CVMP[2] guidance. Due to the nature of the application, no other toxicological assessment was required.

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. 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.
- Any uneaten medicated 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.
- In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Environmental Safety

The applicant has submitted a Phase I ERA conducted in accordance with current VICH guidelines. The assessment has concluded at question 3 of the decision tree, as the product will be used in non-food producing animals only. A Phase II ERA was not required.

[2] CVMP

The disposal advice and environmental warnings found under section 6.6 of the SPC and in the package leaflet are as follows:

- Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
- The disposal advice on the outer and immediate package is the abridged version.
- Dispose of waste material in accordance with local requirements.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Pharmacology

The applicant has conducted a study to determine the comparative bioequivalence of the product versus the reference product. 24 Beagle dogs (12 male and 12 female) were used for the study. Each product was administered at a dose of 0.2 mg/kg by oral gavage, followed by a 14 day wash-out period. The dogs were then administered the alternative product in a crossover study. No adverse reactions were observed. The final study report concludes that bioequivalence has been demonstrated.

Tolerance in the Target Species

The applicant has conducted a literature review of the target animal tolerance studies, which did not identify any evidence of the lack of tolerance in the target species.

Resistance

Due to the legal base of the application, no resistance data is required.

IV.II. Clinical Documentation

Laboratory Trials

No clinical data has been submitted. Due to the legal base of the application, this is acceptable.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

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