Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Metaxx 0.25 mg Chewable Tablets for Cats

Date Created: January 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Metaxx 0.25 mg Chewable Tablets for Cats
Applicant	Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden, 3449 The Netherlands
Active substance	Meloxicam
ATC Vetcode	QM01AC06
Target species	Cats
Indication for use	Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures, e.g. orthopaedic and soft tissue surgery. Alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders.

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(1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	19/10/2022

I. SCIENTIFIC OVERVIEW

This was determined a generic hybrid application since there is a quantitative change to the active substance with regard to the reference medicinal product has been made. The quality / safety / efficacy aspects of this product are identical to Metacam 0.5 mg/ml.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains meloxicam and the excipients microcrystalline cellulose, chicken flavour, crospovidone (type A), lactose monohydrate, magnesium stearate, colloidal hydrated silica, sodium citrate and dried yeast.

The container/closure system consists of an OPA/aluminium/PVC blister pack with a push-through aluminium lidding. The blister packaging contains a layer of soft aluminium foil with OPA-lacquer on the outside and a PVC-lacquer on the inside. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation is 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: mixing, sieving 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.

All excipients, except chicken flavour and dried yeast which comply with in-house monographs, are described in Ph. Eur.

II.C.4. Substances of Biological Origin

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

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, dissolution, tablet mass, resistance to crushing of tablet, uniformity of dosage units, identification and assay of meloxicam, related substances and microbiological quality.

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: 3 years
Shelf life of divided tablets after first opening the immediate packaging: 3 days

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Not required due to the legal basis of the application.

Toxicological Studies

Not required due to the legal basis of the application.

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 product may cause hypersensitivity reactions. People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

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

Not required due to the legal basis of the application.

Tolerance in the Target Species

Not required because of the legal basis of the application.

IV.II. Clinical Documentation

Laboratory Trials

Not required due to the legal basis of the application. Bioequivalence was established in a conducted study.

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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