College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Metaxx 0.25 mg chewable tablets for cats

NL/V/0382/001/DC

Created:

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0382/001/DC
Name, strength and pharmaceutical form	Metaxx 0.25 mg chewable tablets for cats
Applicant	Alfasan Nederland BV Kuipersweg 9 3449 JA Woerden The Netherlands
Active substance(s)	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.

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MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(3) of Directive 2001/82/EC as amended (Hybrid).
Date of completion of the original decentralised procedure	23 November 2022
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, NO, PL, PT, RO, SE, SI, SK, UK(NI)

I. SCIENTIFIC OVERVIEW

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; the reactions observed are indicated in the SPC.
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 risk/benefit analysis is in favour of granting a marketing authorisation.

The product is authorized in accordance with Article 13(3) of Directive 2001/82/EC as amended. The reference product for this application is Metacam 0.5 mg/ml oral suspension for cats and guinea pigs (REG NL 10570/ EU/2/97/004) marketed in the Netherlands by Boehringer Ingelheim Vetmedica GmbH since 1998.

II. QUALITY ASPECTS

A. Qualitative and Quantitative particulars of the constituents

The proposed product concerns a chewable tablet for cats and is a generic (hybrid) veterinary medicinal product. It is described as light brown, slightly dotted, circular, biconvex tablet with a cross shaped break line on one side. It contains the active substance meloxicam (0.25 mg/tablet) and the excipients cellulose, microcrystalline, crospovidone, lactose monohydrate, magnesium stearate, silica, colloidal hydrated, sodium citrate, yeast (dried) and chicken flavour. The chewable tablets can be divided into two or four equal parts.

The product is to be packed in OPA/aluminium/PVC blisters with an aluminium lidding.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

The manufacturing formulae for lowest (32 kg) and highest (320 kg) batch sizes of the proposed batch size range are presented. The manufacturing process consists of blending, tabletting and packaging. Based on the low content of active substance in the proposed product (≤ 2%), the manufacturing process is regarded as non-standard process. The tests performed during manufacture are described and regarded to be acceptable. Suitable validation results on two production scale batches have been provided. In view of the available process validation data and the experience of the manufacturer the commitment to submit process validation data on one additional production scale batch post authorisation is accepted.

C. Control of Starting Materials

The active substance is meloxicam, an established substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice. Micronized drug substance is used in the manufacturing process.

For the active substance an ASMF and a CEP are used. A copy of the Applicant's version of the ASMF has been provided by the applicant. The ASMF has already been evaluated and approved in a centralised worksharing procedure and the assessment of the ASMF has been adopted in this decentralised procedure. A commitment to submit the newly available version of the ASMF (version III from July 2022) as a post approval variation has been presented.

A copy of the currently valid version of the CEP, with a signed declaration of access, has been provided.

The active substance specification is considered acceptable. Batch analytical data demonstrating compliance with the proposed specification have been provided.

Each of the excipients complies with the relevant Ph. Eur. monograph, except for chicken flavour and yeast (dried). In-house specifications for the flavouring agents are presented.

It is confirmed that there are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control tests carried out at the intermediate stages of the manufacturing process

Not applicable.

E. Tests on the Finished Product

The finished product release and shelf life specifications control the relevant parameters for the pharmaceutical form. The tests in the specification and their limits are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data of two batches have been provided demonstrating compliance with the specification.

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F. Stability tests

It is confirmed that the retest period and storage conditions as defined in the ASMF and on the CEP for meloxicam are adopted. The retest period is 5 years, stored in the selected packaging materials.

Stability data on two batches of the finished product have been provided, which were stored at 25 °C/60%RH (36 months) and at 40°C/75%RH (6 months). The submitted data covers the proposed shelf life period (3 years) and the product is considered relatively stable.

It is committed that an additional production batch will be placed on long term stability studies through the proposed shelf life and on accelerated studies for six months.

An in-use stability study was performed with two batches, of which one was approaching end of shelf life. The tablets were stored unprotected on a glass disc for 3 days at long term conditions. All evaluated parameters were conform specifications and no significant changes were noted.

G. Other Information

None

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III. SAFETY ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A

User Safety

The product is authorized in accordance with Article 13(3) of Directive 2001/82/EC as amended. Bioequivalence with the reference product has been demonstrated. The safety claims for this product are equivalent to those of the reference product.

Warning statements and precautions as listed in the product literature are based on those of the reference product and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users and the environment.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

III.B Residues documentation

Not applicable as the product is intended for cats.

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IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a hybrid application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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 Heads of Veterinary Medicines Agencies website (www.HMA.eu).

This section 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.

None.