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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

RHEUMOXIDYL 15 MG/ML ORAL SUSPENSION FOR HORSES

Date: 27/12/2022

PRODUCT SUMMARY

EU procedure number	FR/V/0447/001/DC
Name, strength and pharmaceutical form	RHEUMOXIDYL 15 MG/ML ORAL SUSPENSION FOR HORSES
Applicant	C & H GENERICS C/O MICHAEL MCEVOY & CO., SEVILLE HOUSE, NEW DOCK STREET GALWAY IRELAND
Active substance(s)	Meloxicam
ATC vetcode	QM01AC06
Target species	Horses
Indication for use	Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application	Generic application in accordance with Article 13.1 Generic Application (Directive No 2001/82/EC)
Date of completion of the original decentralised procedure	23/11/2022
Concerned Member States for original procedure	BE, DE, NL

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the slight reactions observed are indicated in the SPC.

The VMP is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains 15 mg/ml meloxicam and the excipients saccharin sodium, carmellose sodium, silica colloidal anhydrous, citric acid monohydrate, sorbitol liquid (non-crystallizing), disodium phosphate dodecahydrate, sodium benzoate, honey aroma and purified water.

The container/closure system a high density polyethylene bottle with a polyethylene dropper and a polyethylene tamper proof child resistant closure. A polypropylene measuring syringe is joint to the bottle.

The choice of the formulation and presence of preservative are justified.

The VMP 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 VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

C. Production and control of starting materials

The active substance is meloxicam, an established substance described in the European Pharmacopeia. 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.

Scientific data and 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.

D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable.

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 VMP.

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.

F. Stability tests

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 VMP throughout its shelf life when stored under the approved conditions.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

A. Safety tests

Pharmacological studies

See section 4.A

Toxicological studies

As this is a generic application in accordance with Article 13.1 (Directive No 2001/82/EC) and bioequivalence with the reference VMP has been demonstrated, results of toxicological tests are not required.

User safety

As this is a generic application in accordance with Article 13.1 (Directive No 2001/82/EC) and bioequivalence with the reference VMP has been demonstrated, identical user safety precautions are advised as for the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP will be used to treat a small number of animals in a flock or herd.

B. Residues documentation

Residue tests

This application for marketing authorisation is being made according to the provisions of Article 13.1 (a) (iii) of Directive 2001/82/EC as amended by Directive 2004/28/EC.

It is a generic application of the reference product Metacam 15 mg/mL oral suspension for horses. No residue depletion studies were conducted.

Maximum Residue Limits

Meloxicam is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Species	Decision	Marker residue	Tissue	MRL	Regulation
Equidae	Annex I	Meloxicam	Muscle Liver Kidney	20 µg/kg 65 µg/kg 65 µg/kg	1805/2006 in 07/12/06

Withdrawal Periods

This procedure is a generic application for a product administered by oral route. As bioequivalence is demonstrated between the test product and the reference product, it is not necessary to perform residue depletion studies with the test product. The established withdrawal periods of the reference product are applied.

Species	Tissues	Withdrawal periods
Equidae	Meat & offal	3 days
	Milk	Not authorised for use in animals producing milk for human consumption

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application in accordance with Article 13.1 (Directive No 2001/82/EC) 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.

A. Pre-Clinical Studies

Pharmacology

The Applicant presented the results of a well-designed GLP-compliant *in vivo* bioequivalence study, which compared the pharmacokinetics of meloxicam in horses. Plasma concentrations of meloxicam were measured following single oral administration of the candidate and reference (Metacam 15 mg/mL oral suspension) formulations with blood samples collected at appropriate time points.
Based upon the results of the bioequivalence study conducted and the subsequent statistical analysis, it is accepted that the candidate product formulation can be considered bioequivalent to the reference product formulation.

Tolerance in the target species of animals

As this is a generic application in accordance with Article 13.1 (Directive No 2001/82/EC) and bioequivalence with the reference VMP has been demonstrated, tolerance studies are not required. The tolerance of this VMP are equivalent to those of the reference VMP.

The product literature accurately reflects the type and incidence of adverse effects, which might be expected.

B. Clinical trials

As this is a generic application according to Article 13(1) of Directive 2001/82/EC, as amended by Directive 2004/28/EC, 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.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.