ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Animeloxan 1.5 mg/ml Oral Suspension for Dogs

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0267/001/DC
Name, strength and pharmaceutical form	Animeloxan 1.5 mg/ml Oral Suspension for Dogs
Applicant	aniMedica GmbH, Im Sudfeld, 48308 Senden Bosensell, Germany
Active substance	Meloxicam
ATC Vetcode	QM01AC06
Target species	Dog
Indication for use	Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies (veterinary) (HMA(v)) website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	30 April 2008
Date product first authorised in the Reference Member State (MRP only)	n/a
Concerned Member States for original procedure	Austria Denmark Hungary The Netherlands Poland Slovenia

I. SCIENTIFIC OVERVIEW

The product is an oral suspension containing 1.5 mg/ml meloxicam and is indicated for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.
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 slight 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 benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains the active substance meloxicam and excipients microcrystalline cellulose sodium carmellose, glycerol, sorbitol, liquid (non-crystallising), xylitol, sodium benzoate, sodium dihydrogen dhosphate dihydrate,

saccharin sodium, honey flavour IFF RS 8008, citric acid monohydrate and purified water.

The container/closure system comprises a high density polyethylene bottle with polypropylene inner cap, nozzle and outer cap. A measuring device, a: polypropylene syringe, is also provided. Three different sized bottles are authorised, 10 ml, 32 ml and 100 ml. The particulars of the containers and controls performed were provided and conform to the regulation.

The choice of the formulation and 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.

B. Method of Preparation of the Product

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

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

C. Control of Starting Materials

The active substance is meloxicam. Supporting data have been provided in the form of a European Drug Master File (EDMF). It is considered that the manufacturing process is adequately controlled and the active substance specification has been suitably justified.

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.

Excipients, apart from the honey flavour IFF RS 8008, are the subject of monographs in the European Pharmacopoeia. Compliance with the requirements of the pharmacopoeia was therefore applied as the specification for each of these ingredients. In the case of the honey flavour IFF RS 8008, compliance with an in-house specification has been demonstrated.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

There are no intermediate products.

F. 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, were justified and were considered appropriate to adequately control the quality of the product. Satisfactory validation data for the analytical methods were provided.

Batch analytical data from the proposed production sites were provided demonstrating compliance with the specification.

G. Stability

The stability of meloxicam is discussed in the active substance master file (ASMF) assessment report. 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

Stability data on the finished product were provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 6 months

Special precautions for storage

Do not store above 30ºC

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological tests are not required.

The pharmacological aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users, the environment and consumers.

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

The toxicological aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users, the environment and consumers.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline that considered all of the potential routes of exposure and included an appraisal of the exposure to the user. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that further assessment was not required. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

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

Tolerance in the Target Species of Animals

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

Resistance

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

IV.B Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, clinical 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 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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