ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Animeloxan 5 mg/ml Solution for Injection for Dogs and Cats

PuAR correct as of 22/08/2018 when RMS was transferred to DE. Please contact the RMS for future updates

Updated: December 2017

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0377/001/DC
Name, strength and pharmaceutical form	Animeloxan 5 mg/ml Solution for Dogs and Cats
Applicant	aniMedica GmbH Im Suedfeld 9 48308 Senden-Boesensell Germany
Active substance	Meloxicam
ATC Vetcode	QM01AC06
Target species	Dogs, Cats
Indication for use	Dogs: Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery. Cats: Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

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	Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	26th October 2011.
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	Austria, Germany, Poland

I. SCIENTIFIC OVERVIEW

This was a decentralised application for a generic product, submitted in accordance with article 13 (1) of Directive 2001/82/EC, as amended. The reference product is Metacam 5 mg/ml Solution for Injection Dogs and Cats. The indication in dogs is for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders and the reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery. In cats, the indication is for Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

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.[1]

The product 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 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. QUALITY ASPECTS

A. Composition

The product contains 5 mg/ml meloxicam and excipients N-Methyl 2-pyrrolidone, ethanol, anhydrous sodium hydroxide, hydrochloric acid, dilute and water for injection.

The container/closure system consists of clear glass (Type I) bottles of 10 ml 20 ml and 25 ml, closed with bromobutyl rubber stoppers and aluminium /PP caps. The product is available in boxes containing 1 x 10 ml or 5 x 10 ml and 1 x 20 ml or 5 x 20 ml, and 1 x 25 ml or 5 x 25 ml, not all pack sizes may be marketed. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the 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, 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 comply with appropriate Ph. Eur monographs.

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

Not applicable.

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, 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 visual analysis, identification of active substance, extractable volume, pH, sterility and related substances.

G. 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. Long term, intermediate and accelerated studies demonstrated the appropriateness of the product to retain a two year shelf-life.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Shelf-life of the product as stored for sale: 3 years.
Shelf-life of the product after first opening: 28 days.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

III.A Safety Testing

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, (CVMP[2] EMEA/CVMP/543/03-Final), citing that only professionals (veterinarians, farmers) will use the product, and that the main route of exposure is the dermal route. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product:-

- Accidental self-injection may give rise to pain. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product. In case of accidental self-injection, seek medical

[2] CVMP – The Committee for Medicinal Products for Veterinary Use.

advice immediately and show the package leaflet or the label to the physician.
- If accidental skin contact occurs, wash the affected area thoroughly.
- Wash hands after use.
- In view of the risk of accidental self-injection and the known adverse class-effects of NSAIDs and other prostaglandin inhibitors on pregnancy and/or embryofoetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.

Ecotoxicity

The applicant provided a Phase I environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The assessment concluded that environmental exposure will not be large, as the product will only be used to treat individual animals.

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)

Although this was a generic product, bioequivalence and tolerance studies were required in order to permit the use of the product via the subcutaneous route.

IV.A Pre-Clinical Studies

Pharmacology

Bioequivalence studies were performed in both dogs and cats.

Dogs

A suitable number of animals were used in a 2 x 2 two period cross-over study, using the test product Animeloxan 5 mg/ml Solution for Injection Dogs and Cats and the reference product Metacam 5 mg/ml Solution for Injection Dogs and Cats. The products were delivered subcutaneously at 0.2 mg meloxicam/kg bodyweight, and there was a wash-out period of 14 days. Blood plasma levels of the active substance were regularly monitored. AUC and Cmax confidence intervals demonstrated bioequivalence between the two products.

Cats

A suitable number of animals were used in a 2 x 2 two period cross over study, using the test product Animeloxan 5 mg/ml Solution for Injection Dogs and Cats and the reference product Metacam 5 mg/ml Solution for Injection Dogs and Cats. The products were delivered subcutaneously at 0.3 mg meloxicam/kg bodyweight, and there was a wash-out period of 14 days. Blood plasma levels of

the active substance were regularly monitored. AUC and Cmax confidence intervals demonstrated bioequivalence between the two products.

Tolerance in the Target Species of Animals

Good tolerance was established in both target species. Any adverse reactions are cited on the SPC and product literature.

IV.B Clinical Studies

Laboratory Trials

As this was a generic application submitted under Article 13 (10 of Directive 2001/82/EC as amended, and a reference product was already established, no data were required for this section.

Field Trials

As this was a generic application submitted under Article 13 (10 of Directive 2001/82/EC as amended, and a reference product was already established, no data were required for this section.

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 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.

(www.gov.uk/check-animal-medicine-licensed)