Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Company:
Richter Pharma AG

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Ketamidor – 100 mg/ml Solution for Injection

AT/V/0009/001/DC

Date: 23/11/2012

Last update: 05/12/2018

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

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DVR: 2112611

Module 1-3 reflect the scientific discussion for the approval of Ketamidor. The procedure was finalised at 21/11/2012. For information on changes after this date please refer to module 4.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	AT/V/0009/001/DC
Name, strength and pharmaceutical form	Ketamidor 100 mg/ml solution for injection [AT, BE, EL, ES, FR, HU, IE, NL, PT, UK] Ketador vet. 100 mg/ml solution for injection [DK, IS, SE, FI]
Applicant	Richter Pharma AG Feldgasse 19 4600 Wels - Austria
Active substance	Ketamine (as hydrochloride)
ATC Vetcode	QN01AX03
Target species	Horse, cattle, pig, dog, cat.
Indication for use	To be used as a sole agent for restraint and minor surgical procedures in the cat, where muscle relaxation is not required. To be used to induce anaesthesia: a) in combination with detomidine in the horse. b) in combination with xylazine in the horse, in cattle, dog and in the cat. c) in combination with azaperone in the pig. d) in combination with medetomidine in the dog and cat.

MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application*	Generic application art. 13(1)
Reference medicinal product	Ketamin "Richter" 100 mg/ml - Injektionslösung für Tiere marketed by Richter
Date of completion of the original decentralised procedure	21/11/2012
Concerned Member States for procedure	BE, DK, EL, ES, FI, FR, HU, IE, IS, NL, PT, SE, UK

* The original procedure (AT/V/0009/001/DC) was authorised according to Art 13(1) (generic data). The data for this included line extension procedure (AT/V/0009/001/DX/001) are own data (bibliographic) and the extension application is therefore hybrid (Art. 13 (3)). The discussion in CMDv and EC is still ongoing.

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

II. QUALITY ASPECTS

A. Composition

The product contains ketamine 100 mg/ml and the excipients benzethonium chloride and water for injection.

The container/closure systems are 10 ml and 50 ml clear glass vials, type I, with bromobutyl rubber stopper and aluminium crimp cap.

The particulars of the containers and controls performed are provided and conform to the regulation.

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 ketamine hydrochloride, an established active substance which is described in the European Pharmacopoeia. It is considered that the manufacturing process is adequately controlled and the active substance specification has been suitably justified.

Certificate of Suitability has been provided.

All the excipients are the subject of monographs in the European Pharmacopoeia and are provided to that standard.

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.

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.

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.

An in-use stability of 28 days is supported.

H. Genetically Modified Organisms

Not applicable.

J. Other Information None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, data on pharmacodynamics and pharmacokinetics are not required. The data submitted are in accordance with the requirements of the applicable European bioequivalence guideline.

Toxicological Studies

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, this information is not required.

User Safety

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, a detailed user safety is not required.
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 no further assessment is 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.

III.B Residues documentation

No residue depletion studies were conducted because, in accordance with the data requirements of the applicable European bioequivalence guideline, it was demonstrated that the product is a generic of “Ketamidor 100 mg/ml Injektionslösung für Tiere” and that the residue depletion profile will be the same.

MRLs

Ketamine hydrochloride is listed in Table 1 of Council Regulation 37/2010. No MRLs were set.

Withdrawal Periods

Based on the data provided above, withdrawal periods of zero days for meat and offal and zero hours for milk are justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, this information is not required as it has already been presented for the reference product.

Tolerance in the Target Species of Animals

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, this information is not required as it has already been presented for the reference product.

IV.B Clinical Studies

Laboratory Trials

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, this information is not required as it has already been presented for 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 veterinary Heads of 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.

Summary of change	**Approval date**
This marketing authorization was renewed unlimited.	11/10/2017
Line Extension (The original procedure (AT/V/0009/001/DC) was authorised according to Art 13(1) (generic data). The data for this included line extension procedure (AT/V/0009/001/DX/001) are own data (bibliographic) and the extension application is therefore hybrid (Art. 13 (3)). The discussion in CMDv and EC is still ongoing.)	21/11/2018