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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Lidor 20 mg/ml solution for injection for horses, dogs and cats

DATE: 23/02/2018

MODULE 1

PRODUCT SUMMARY

EU Procedure number	**FR/V/0318/001/DC**
Name, strength and pharmaceutical form	**Lidor 20 mg/ml solution for injection for horses, dogs and cats**
Applicant	**Richter Pharma AG, Feldgasse 19, 4600 Wels, Austria**
Active substance(s)	**Lidocaine (as hydrochloride monohydrate)**
ATC Vetcode	**QN01BB02**
Target species	**Horses, dogs and cats.**
Indication for use	**Horses:** **Ophthalmic contact anaesthesia, anaesthesia by infiltration, intra-articular anaesthesia, perineural anaesthesia and epidural anaesthesia.** **Dogs, cats:** **Anaesthesia in ophthalmology and dentistry, anaesthesia by infiltration and epidural anaesthesia.**

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 (1) of Directive 2001/82/EC, as amended.
Date of completion of the decentralised procedure	21/12/2017

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, 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 20 mg of lidocaine (as hydrochloride monohydrate) and the following excipients: methyl parahydroxybenzoate (E218), propyl parahydroxbenzoate, sodium chloride, sodium hydroxide, hydrochloric acid concentrated and water for injections.

The packaging of the finished product is as described on the SPC. 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 lidocaine hydrochloride monohydrate, an established substance described in the European Pharmacopoeia. 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.

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

A re-test period for the active substance is set in the certificate of suitability issued by EDQM.

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 shelf-life as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL) (*for pharmaceuticals only*)

III.A Safety Testing

Pharmacological Studies

As this is an application according to Article 13 (1) of Directive 2001/82/EC, and bioequivalence with a reference product has been demonstrated, results of pharmacology and toxicology tests are not required.

Toxicological Studies

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

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

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

III.B Residues documentation

Residue Studies

Given the legal basis of the application, Article 13(1) of Directive 2001/82/EC "Generic", and the fact that the bioequivalence with the reference product can be assumed and according to the MRL status of active substance, lidocaine, it is accepted that a residue depletion study is not required.

MRLs

The active substance, lidocaine, is included in table 1 of the MRL regulation 37/2010, as follows,

Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification	Regulation
Not applicable	*Equidae*	No MRL required	Not applicable	For local-regional anaeshesia only	No entry	37/2010 of 22.12.2009

The composition of the product LIDOR 20 MG/ML SOLUTION FOR INJECTION is acceptable according to the European Regulation (EC) 470/2009

Withdrawal Periods

In order to address the concern relative to consumer safety, the following withdrawal periods were retained:

Meat and offal: 3 days

Milk: 3 days

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13(1) of Directive 2001/82/EC, and bioequivalence with a reference product has been demonstrated, target animal safety and efficacy studies are not required. The target animal safety and 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.