ÚSKVBL
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RMS: CZ

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

LidoBel 20 mg/ml solution for injection

MODULE 1

PRODUCT SUMMARY

EU Procedure number	CZ/V/0140/001/DC
Name, strength and pharmaceutical form	LidoBel 20 mg/ml solution for injection
Applicant	Bela-pharm GmbH & Co. KG, Lohner Str. 19 49377 Vechta, Germany
Active substance(s)	Lidocaine hydrochloride
ATC Vetcode	QN01BB02
Target species	Horses, dogs and cats.
Indication for use	For local/nerve block (regional infiltration) including field block anaesthesia. Superficial anaesthesia of mucous membranes.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13.1of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	2 Mai, 2018
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	AT, BE, EE, ES, FI, HU, IE, IS, LT, LV, NO, PL, PT, RO, SE, SI, SK

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 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.
As this is a generic application, 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.

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

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 20 mg of lidocaine hydrochloride (which is equivalent to 16.23 mg of lidocaine) per ml and the excipients methyl parahydroxybenzoate, propyl parahydroxybenzoate, disodium edetate, sodium chloride, propylene glycol, sodium hydroxide, hydrochloric acid and water for injection.

The container/closure system consists of clear glass vials (type II) closed with bromobutyl rubber stoppers and aluminium caps.

The choice of the presence and levels of preservatives is 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 at a licensed manufacturing site.

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

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is Lidocaine hydrochloride, 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.

Certificate of suitability issued by the EDQM has been provided.

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

D. Control on intermediate products

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

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 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.

F. Stability

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

The in-use shelf-life of the broached product is supported by the data provided.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13.1 of Directive 2001/82/EC as amended results of safety tests are not required.

The formulation of this product is identical to the reference product.

III.A Safety Testing

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.

Environmental Risk Assessment

Phase I

The environmental risk assessment can stop in Phase I, because the product is used in non-food animals like dogs and cats or the product is used to treat a small number of animals in herd – horses. A Phase II ERA is not required.

Conclusion

The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues documentation

Residue Studies

The applicant has submitted the generic application in accordance with Article 13(1) of Directive 2001/82/EC, as amended. No residue depletion studies were required at this case.

MRLs

According to the Annex I of Commission Regulation (EU) No. 37/2010 – following MRLs have been established for the active substance:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Lidocaine	Not applicable	*Equidae*	No MRL required	Not applicable	For local-regional anaesthesia only.	No entry

Withdrawal Periods

Based on information above, the following withdrawal periods were approved:

Withdrawal period(s):

Horse:
Meat and offal: 5 days
Milk: 5 days

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13(1), 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.

IV.B Clinical Studies

Efficacy data have not been presented.

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.