Austrian
Federal Office for
Safety in Healthcare
BASG

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Diazedor 5 mg/ml Injektionslösung für Hunde und Katzen

AT/V/0017/0001/DC

Date: 19/02/2018

Last update: 06/03/2024

Modules 1-3 reflect the scientific discussion for the approval of Diazedor 5 mg/ml Injektionslösung für Hunde und Katzen. The procedure was finalised on 31.01.2018. For information on changes after this date please refer to module 4.

MODULE 1

PRODUCT SUMMARY

EU procedure number	AT/V/0017/0001/DC
Name, strength and pharmaceutical form	Diazedor 5 mg/ml Injektionslösung für Hunde und Katzen
Applicant	Richter Pharma AG Feldgasse 19 4600 Wels Austria
Active substance(s)	DIAZEPAM
ATCvet code	QN05BA01
Target species	dogs and cats
Indication for use	For the short term management of convulsive disorders and skeletal muscle spasms of central and peripheral origin. As part of a pre-anaesthetic or sedation protocol.

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 according to Article 13 (1) of Directive No 2001/82/EC as amended
Reference medicinal product	Diazepam 0,5 % Inietabile
Date of completion of the original decentralised procedure	31.01.2018
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	BE, DE, DK, ES, FI, FR, IE, IT, NL, NO, PT, SE, UK

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 (see 4.6 "adverse reactions").

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

II. QUALITY ASPECTS

II.A Qualitative and quantitative particulars

The product contains:

Diazepam 5.0 mg and the excipients Ethanol 96%, Propylene glycol, Sodium hydroxide (for pH adjustment) and Water for injections.

Cardboard box with colourless glass ampoules with a nominal volume of 2 ml.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

II.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.

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

II.C Control of Starting Materials

The active substance is Diazepam. 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.

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

II.D Control on intermediate products (pharmaceuticals)

Not applicable.

II.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 sites have been provided demonstrating compliance with the specification.

II.F 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.

The claim of stability after broaching is acceptable, for details see section 6.3 of SPC.

II.G Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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.

III.A Safety Testing

Pharmacological Studies

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

Toxicological Studies

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

User Safety

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, a detailed user safety assessment is not required. The safety warnings are the same as for the reference product.

Nevertheless the applicant provided a satisfactory user risk assessment, identifying the risk to the users of the product and the potential routes of exposure. This showed that the most likely routes of exposure to the product would be via

- skin contact
- eye contact
- accidental self-injection
- ingestion.

CONCLUSIONS ON USER SAFETY

This application is made in accordance with Article 13 (1) of Council Directive 2001/82/EC as amended. The product fulfils the requirements for a waiver from bioequivalence studies in accordance with section 7.1.a) as the qualitative and quantitative composition of the test product 'Diazedor 5 mg/ml solution for injection for dogs and cats' and the reference product 'Diazepam 0,5 % Inietabile' is the same in terms of active substance and pharmaceutical form. The proposed formulation is an aqueous solution intended for single intravenous application only. The slight differences regarding the excipients are not considered to influence the availability of diazepam.

The URA is in accordance with current guidance and identifies the users of the product, the hazards associated with its use and the relevant routes of exposure. Skin and ocular exposure and accidental injection are identified as the exposure scenarios of most concern. The proposed user warnings are adequate, hence it is accepted that 'Diazedor 5 mg/ml solution for injection for dogs and cats' will not pose any greater risk to the user than 'Diazepam 0,5 % Inietabile'.

The risks have been identified and appropriate warnings are included in the SPC and product literature.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be is used in non-food animals.

Conclusion:

Based on the data provided, the environmental risk assessment can stop at Phase I, as "Diazedor 5 mg/ml solution for injection for dogs and cats" will be used to treat a small number of non-food animals on an individual basis. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

Warnings and precautions as specified in the product literature are adequate to ensure safety to the environment when the product is used as indicated in the SPC.

III.B Residues documentation

Not applicable.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with the 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.A Pre-Clinical Studies

Pharmacology

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, pharmacodynamic and pharmacokinetic studies are not required.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, tolerance studies are not required.

Adequate warnings and precautions appear on the product literature, for details see section 4.5 of SPC.

IV.B Clinical Studies

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, data on clinical efficacy are not required.

Laboratory Trials

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, laboratory studies are not required as they have already been presented for the reference product.

Field Trials

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, field studies are not required as they have already been presented for the reference product.

The product is efficacious when used according to the SPC.

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 Heads of Veterinary Medicines 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.

Significant changes

Summary of change **(Application number)**	**Approval date**
No changes since marketing authorization.	---