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College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Solupam 5 mg/ml injection for dogs and cats

Created: December 2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0242/001/DC
Name, strength and pharmaceutical form	Solupam 5 mg/ml injection for dogs and cats
Applicant	Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel The Netherlands
Active substance(s)	Diazepam
ATC Vetcode	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 in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	23 October 2018
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, NO, PL, PT, RO, SE, SI, SK, UK

I. SCIENTIFIC OVERVIEW

Solupam is a generic application according to Article 13. The reference product is DIAZEPAM 0,5% Soluzione iniettabile per cani e gatti, marketed in Italy.

II. QUALITY ASPECTS

QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The proposed product is an aqueous veterinary medicinal product for parenteral administration. The product contains 5 mg/mL diazepam as the active substance and the following excipients: benzoic acid, sodium benzoate, propylene glycol, ethanol 96%, benzyl alcohol and water for injections.

The product is packed in clear type I glass vials of 5, 10, 20 and 50 mL, closed with dark grey coated rubber stoppers (Omniflex Plus) and aluminium caps. The glass vials and stoppers are in conformity with Ph. Eur. requirements.

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.

The product is manufactured using conventional manufacturing techniques. Process validation results for two 50 L small scale production batches, including all fill volumes, have been provided. However, process validation results for one full scale production batch (500 L) will be made available for verification post authorisation by the supervisory authority. The tests performed during production are described.

C. Control of Starting Materials

The active substance is diazepam, an established active substance described in the European Pharmacopoeia (monograph 0022). For the active substance the CEP procedure is followed. 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.

No materials of animal origin are contained or used in the manufacturing process of the veterinary medicinal product.

D. Control on intermediate products

Not applicable.

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 the corresponding acceptance criteria are considered acceptable. Non-routine testing for related substances at release is considered to be acceptable.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been submitted, demonstrating compliance with the finished product specification

F. Stability

A re-test period of the active substance of 60 months is indicated on the CEP when stored in Double LDPE bag (outer black) placed in a HPDE container.

The proposed end of shelf-life limit of 1.5% for degradation product MACB is considered justified. Stability data on the finished product have been provided up to 18 months of storage. Based on the submitted stability data for the drug product, both the proposed shelflife of 2 years and the proposed in-use shelf-life of 56 days can be granted. For the in-use stability study, the end of shelf life results of a repeat challenge test for the efficacy of antimicrobial preservation are awaited.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guidelines. The applicant adopted the warnings and safety measures as recently established for a similar product 'Ziapam 5 mg/ml solution for injection for cats and dogs', REG NL113493, with some slight amendments. The proposed warnings and safety measures are adequate and sufficiently mitigate the risk for the user.

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 used in non-food animals.

IV. CLINICAL ASSESSMENT (EFFICACY)

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

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 Vetrinary 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.

None.