Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
(BVL) Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
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(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Exagon

Date: 11.01.2023

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0155/001/DC
Name, strength and pharmaceutical form	Exagon, 400 mg/ml, solution for injection
Applicant	VetViva Richter GmbH Durisolstraße 14 4600 Wels, Austria
Active substance(s)	Pentobarbital sodium
ATC Vetcode	QN51AA01
Target species	Horses, ponies, cattle, swine, dogs, cats, minks, polecats, hares, rabbits, guinea pigs, hamsters, rats, mice, poultry, pigeons, birds, snakes, tortoises, lizards, frogs
Indication for use	Euthanasia

MODULE 2

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

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 original Decentralised procedure	29.01.2014
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	AT, CZ, DK, EE, EL, ES, FI, FR, IS, IT, 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.

The safety and efficacy aspects of this product are identical to Eutha. The initial application for Eutha was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains pentobarbital sodium 400 mg/ml (eq. to pentobarbital 364.6 mg) as the active substance and the following excipients: propylene glycol, ethanol 96%, benzyl alcohol, patent blue V and water for injection.

The container/closure system is a Type II clear glass vial (100 ml) with Type I bromobutyl rubber stopper and aluminium cap in a cardboard box. 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 pentobarbital sodium, an established active 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

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 a 2-hour stability after dilution with sterile, isotonic NaCl (0.9%)-solution at a mix ratio of 1:1 is based on the demonstration of stability of a batch diluted as described in the posology and stored over a period of 2 hours.

The claim of a stability of 28 days after broaching is based on the demonstration of stability for a batch broached and stored 28 days at 25 °C and protected from light.

H. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product is assumed based on the composition and formulation of the product, results of safety tests are not required.

Pharmacological and toxicology aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to the environment / consumers.

User Safety

The applicant has submitted a user risk assessment, which has broadly been presented in line with guideline EMA/CVMP/543/03-Rev.1. It has been shown, that the use of the product do not pose a relevant health risk for the user, when it is administered according to the warnings and precautions as listed on the product literature.

Environmental Risk Assessment

Based on the data provided, the ERA can stop at Phase I. 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

No residue depletion studies were conducted because the product is only intended for euthanasia on the grounds of animal welfare. Food-producing animals euthanized with Pentobarbital must not be used for human consumption.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product is assumed based on the composition and formulation of the product, 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 Veterinary Medicinal 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.

Quality changes

Summary of change **(Application number)**	**Section updated in Module 3**	**Approval date**
B.II.f.1.d - Change in storage conditions of the finished product (DE/V0155/001/IB/001)	N/A	03/03/2016
B.II.b.1.f - Addition of a manufacturing site for part or all of the manufacturing process of the finished product B.II.b.3.a Minor change in the manufacturing process (DE/V/0155/IB/005/G)	N/A	20/05/2021
E.z - ADMINISTRATIVE CHANGES (Transfer the marketing authorisation in DE from Richter Pharma AG to VetViva Richter GmbH)	N/A	11.01.2023