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

Euthoxin 500 mg/ml Solution for Injection

Date: 18 May 2016

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0263/001/DC
Name, strength and pharmaceutical form	Euthoxin 500 mg/ml solution for injection
Applicant	Chanelle Pharmaceuticals Manufacturing Ltd Loughrea Co. Galway Ireland
Active substance(s)	Pentobarbital-sodium
ATC Vetcode	QN51AA01
Target species	Dogs, cats, minks, polecats, hares, rabbits, guinea pigs, hamsters, rats, mice, chickens, pigeons, ornamental birds, small snakes, tortoises, lizards, frogs, horses, cattle, pigs
Indication for use	For 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(3) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	27 January 2015
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	AT, BE, BG, DK, FI, FR, EL, ES, HR, HU, IE, IT, NL, PL, PT, RO, 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.
The safety and efficacy aspects of this product are identical to the original product. The initial application for the original product was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains pentobarbital sodium 500 mg/ml (eq. to pentobarbital 455.7 mg) as the active substance and the following excipients: erythrosine red E127, propylene glycol and water for injections.

The container/closure system is a 100 ml amber glass vial composed of hydrolytic class I glass with pink bromobutyl stopper and lacquered aluminium crimped cap.

The vial is placed 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.

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

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 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.

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 a 28 day stability after broaching is based on the demonstration of stability for a batch broached and stored 28 days at +25°C.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

For generics, insert in the relevant sections as appropriate:

As this is a generic application according to Article 13(3) of Directive 2001/82/EC as amended, and bioequivalence with a reference product is taken for granted, safety studies are not required.

The safety 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 users / the environment / consumers.

Environmental Risk Assessment

Phase I

The environmental risk assessment can stop in Phase I because the product is used in individual animals only. Treated animals will not enter the food chain.

Conclusion

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

The product is only intended for euthanasia on grounds of animal welfare. There is no withdrawal period for such a product. Adequate measures should be taken to ensure that carcases and edible products of the animals do not enter the food chain and are not used for human or animal consumption. Suitable information is included in the SPC of the product.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13(3) of Directive 2001/82/EC as amended, and bioequivalence with a reference product is taken for granted, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

As Euthoxin 500mg/ml and the reference product have the same pharmaceutical form, the same active ingredient and are assumed to be bioequivalent, the applicant did not provide pre-clinical data according to Art. 13(3) of Directive 2001/82/EC. The pre-clinical particulars for this product are equivalent to those of the reference product.

IV.B Clinical Studies

As Euthoxin 500mg/ml and the reference product have the same pharmaceutical form, the same active ingredient and are assumed to be bioequivalent, the applicant did not provide clinical data according to Art. 13(3) of Directive 2001/82/EC. The clinical particulars 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.

<None>