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)

Final

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

OESTRACTON 52.4 µg/ml

Date: 20 February 2014

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0154/001/DC
Name, strength and pharmaceutical form	OESTRACTON 52.4 µg/ml, solution for injection for cattle, horses, pigs
Applicant	VetCom-pharma GmbH Seestrasse 6 AT-6900 Bregenz AUSTRIA
Active substance(s)	Gonadorelin[6-D-Phe]acetate
ATC Vetcode	QH01CA01
Target species	Cattle (cow), Horse (mare), Pig (sow)
Indication for use	Control and stimulation of reproduction and improvement of conception rates in cattle and pigs. Treatment of ovarian-related fertility disorders or dysfunctions in cattle and horses. Cattle: - Ovulation induction in case of delayed ovulation due to LH-deficiency - Ovulation synchronization following oestrus synchronisation - Stimulation of the ovaries during the puerperal period from Day 12 post partum - Ovarian cysts (due to LH-deficiency). Horses: - Acyclia and anoestrus due to LH-deficiency - Ovulation induction (shortening of oestrus).

	Pigs: - Ovulation synchronization in association with a PMSG for timed insemination as part of a timed insemination-regime

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	25.09.2013
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	BE, CZ, FR, HU, IE, NL, 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 Oestracton (BVL ENR 2400215). The initial application for Oestracton 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 52.4 µg/ml of Gonadorelin[6-D-Phe]acetate and the excipients methyl-4-hydroxybenzoate, sodium acetate, acetic acid and water for injection.

The container/closure system consists of colourless type I glass injection vials with chlorobutyl rubber stoppers and aluminium caps.

The choice of the formulation and the presence of the preservative are 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.

C. Control of Starting Materials

The active substance is Gonadorelin[6-D-Phe]acetate, an established active substance. 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.

Scientific data have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control on intermediate products (pharmaceuticals)

There are no intermediate products.

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

The active substance is fully tested to ensure compliance with its specification immediately prior to its use in manufacture of the product.

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 14 days/28 days stability after broaching is based on the demonstration of stability for batches broached and stored at 2 °C – 8 °C through 2 weeks for the 10 ml vials and 4 weeks for the 50 ml vials.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This is a generic application according to Article 13. As the identity with the reference product has been demonstrated, toxicological studies are not required.

The provided user safety assessment is in compliance with the relevant guideline. Possible routes of exposure as skin contact or accidental self-injection have been identified. The applicant postulates that effects on the female reproductive tract are possible and the proposed warnings address the potential exposure of the operator to the product. 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 of the peptide nature and the degradation of the active ingredient.

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

Residue Studies

No residue depletion studies were conducted because Oestracton has the same qualitative and quantitative composition in active substance and its excipients as well as the same pharmaceutical form as the reference preparation.

MRLs

Gonadorelin[6-D-Phe] (= D-Phe^6-Luteinising-Hormone-Releasing-Hormone) is listed for all food producing species in Table 1 of CR (EU) No. 37/2010 as substance for which no MRL is required.

The excipients, Methyl-4-hydroxybenzoate and Acetic acid (E 260, falling under substances with an E-number) are listed in Table 1 of CR (EU) no 37/2010 for all food producing species as substances for which no MRL is required. Both substances are classified as harmless.

Withdrawal Periods

Based on the data provided above, the same withdrawal period as authorised for the reference product are justified:

Cattle, Horse, Pig	Meat and offal:	Zero days
Cattle, Horse	Milk:	Zero days

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 and the identity 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.

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>