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

Gonavet Veyx

Date: 29 Mai 2015

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0158/001/DC
Name, strength and pharmaceutical form	Gonavet Veyx, 50 µg/ml, solution for injection
Applicant	Veyx-Pharma GmbH Soehreweg 6 34639 Schwarzenborn Germany
Active substance(s)	Gonadorelin[6-D-Phe]
ATC Vetcode	QH01CA01
Target species	Cattle, Pig, Horse
Indication for use	Control and stimulation of reproduction in cattle and pigs. Treatment of ovarian-related fertility disorders or dysfunctions in cattle and horses.

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	22.01.2015
Date product first authorised in the Reference Member State (MRP only)	N.A:
Concerned Member States for original procedure	AT, BE, BG, CZ, EE, EL, ES, FR, HU, HR, IE, IS, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, 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 product is safe for the user, the consumer of foodstuffs from treated animals, and for the environment, when used as recommended. Suitable user warnings are indicated in the SPC.

The safety and efficacy aspects of this product are identical to Gonavet Veyx. The initial application for Gonavet Veyx 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 50 µg/ml Gonadorelin[6-D-Phe] and the preservative chlorocresol in water for injections. Sodium hydroxide and/or glacial acetic acid are used for pH adjustment.

The container/closure system is a colourless glass vial, with a rubber stopper and an aluminium cap.

The presence of the preservative is 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] (as 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.

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

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

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 days stability after broaching is based on the demonstration of stability for a batch broached and stored at 25°C±2°C through a 4 weeks period.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application to a reference product from the same company that has been authorised in March 2004 on the basis of a complete dossier in all target animals, results of toxicological or residue studies are not required.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users, the environment and consumers.

Environmental Risk Assessment

Phase I

The environmental risk assessment can stop in Phase I because the product will be intensively metabolised in the treated animals and is not expected to reach the environment as intact compound. Hence, the product is not expected to pose any risk to the environment when used as recommended.
A Phase II ERA is not required.

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 the test product is bioequivalent to the reference product with identical formulation and manufacturing process.

MRLs

The active compound in Gonavet Veyx is included in Table 1 of the Annex to Commission Regulation (EU) No. 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
D-Phenylalanine(6)–luteinisinghormone releasing hormone	Not applicable	All food producing species	No MRL required	Not applicable	No entry	No entry

For the preservative excipient chlorocresol the CVMP recommended the inclusion in Annex 1 of CR (EU) No. 37/2010 for all food producing species and no ADI was established. There is no risk for consumers because chlorocresol is rapidly metabolised and excreted. Chlorocresol has no potential to accumulate in tissues and is of low toxicity. No MRLs were set.

Withdrawal Periods

Based on the data provided above, the following withdrawal periods are justified:

Cattle, pigs, horses:	Meat and offal:	0 days
Cattle, horses:	Milk:	0 hours

IV. CLINICAL ASSESSMENT (EFFICACY)

As Gonavet Veyx 50 µg/ml Solution for Injection for Cattle, Pigs and Horses is a generic to a reference product from the same company, efficacy studies were not

required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Pharmacology

Gonavet Veyx is an aqueous solution containing 50µg/ml gonadorelin [6-D-Phe], which is a synthetic analogue of the natural gonadotropin releasing-hormone, and 1mg/ml chlorocresol as preservative. Gonadorelin [6-D-Phe] – like the natural GnRH – induces LH and FSH release from the pituitary and stimulates via these hormones ovulation during oestrus. The responsiveness of the ovary to GnRH is highest during oestrus. Its secretion is inhibited by progesterone; that is during di-oestrus and during pregnancy.

Tolerance in the Target Species of Animals

No adverse effects were reported from clinical studies with the identical reference product.

IV.B Clinical Studies

All indications claimed for Gonavet Veyx 50 µg/ml Solution for Injection for Cattle, Pigs and Horses in the target animals - ovulation induction in case of delayed ovulation due to LH-deficiency, stimulation of the ovaries during the puerperal period, ovarian cysts, anoestrus and ovulation synchronisation and timed insemination – are authorised for the reference product. Because of the identity of Gonavet Veyx and the reference product, full reference has been made to the latter in respect of all clinical aspects.

In addition, to improve information on certain treatment aspects, the applicant has inserted ”Special information” in chapter 4.9 of the SPC and in chapter 8 of the package leaflet. In these sections treatment regimes for oestrus and ovulation synchronisation and timed insemination in cows, gilts and sows are indicated, which consist of the combined use of Gonavet Veyx and other hormonal products. Data to substantiate these recommendations have been provided by the applicant.

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

VI. 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).