College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

NL/V/0176/001/DC

Porceptal 4 micrograms/ml solution for injection for pigs

Created: November 2013
Updated: January 2020

MODULE 1

PRODUCT SUMMARY

Dutch Registration number	REG NL 112802
EU Procedure number	NL/V/0176/001/DC
Name, strength and pharmaceutical form	Porceptal 4 micrograms/ml solution for injection for pigs
Applicant	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer The Netherlands
Active substance(s)	Buserelin
ATCVet code	H0ICA90
Target species	Pig
Indication for use	Induction of ovulation after oestrus synchronisation by weaning (sows) or by administration of a progestin (gilts) to be used as part of a single fixed time artificial insemination program.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website:

- http://mri.medagencies.org/veterinary/

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 September 2013
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IS, IT, LT, LU, LV, NO, PL, PT, RO, SI, SK, UK

I. SCIENTIFIC OVERVIEW

Porceptal 4 micrograms/ml solution for injection for pigs 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 Porceptal 4 micrograms/ml solution for injection for pigs are based on demonstrated bioequivalence with the Dutch European reference product Receptal, solution for injection (REG NL 5327 and line extension REG NL 105583).
Porceptal 4 micrograms/ml solution for injection for pigs is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Warnings statements and precautions are adopted from the reference product.
Additional user safety statements have been added, based on increased knowledge and the current state of science.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains 0.0042 mg/ml buserelin acetate and the following excipients; benzyl alcohol, sodium chloride, sodium dihydrogen phosphate monohydrate, sodium hydroxide, hydrochloric acid and water for injection

The product is packed in colourless type I glass vials of 2.5 ml, 5 ml, 10 ml or colourless type II glass vials of 50 ml, closed with an ETFE laminated bromobutyl rubber stopper (2.5 ml and 5 ml vials) or a bromobutyl rubber stopper (10 ml and 50 ml vials) and an aluminium crimp cap.

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. Reference to process validation data has been made.

The tests performed during production are described.

C. Control of Starting Materials

The active substance is buserelin acetate, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice and has a CEP.

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.

The excipients are in conformity with compendial requirements.

The glass vials and stoppers are in conformity with the Ph.Eur. requirements.

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

Adequate in-process specifications for Porceptal have been provided.

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

The retest period of the active substance and storage conditions are included on the CEP. 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. The proposed storage conditions are based on the stability data and the innovator product and are acceptable.

The claim of a 28 days stability period after broaching has been justified, as well as the storage conditions of the opened product.

H. Genetically Modified Organisms

None.

J. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, results of pharmacological, toxicological, user safety and residues tests were not required. These aspects are identical to the reference product.

Warnings and precautions as listed on the product literature are based on those of the reference product and are adequate to ensure safety of the product to users / the environment / consumers. Additional user safety statements have been added, based on increased knowledge and the current state of science.

User Safety

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

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because bioequivalence with the reference product has been demonstrated. Besides, buserelin is listed in table 1 (allowed substances) of Regulation EU 37/2010/EC with no MRL required.

Withdrawal Periods

The withdrawal periods are the same as stated for the reference product:
Meat and offal: zero days

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are identical to those related to the species pig in the reference product: “Induction of ovulation after oestrus synchronisation by weaning (sows) or by administration of a progestin (gilts) to be used as part of a single fixed time artificial insemination program”.

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 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.

Summary of change	**Section updated**	**Approval date**
Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH (NL/V/xxxx/IA/011/G)	N/A	28 November 2014
Change in immediate packaging of the finished product Change in the manufacturing process of the finished product (NL/V/xxxx/WS/006)	Section II	2 March 2016
CEP update New CEP from a new manufacturer (NL/V/0176/IB/003/G)	N/A	6 October 2016
Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH (NL/V/xxxx/IA/017/G)	N/A	21 November 2016
Renewal (NL/V/0176/001/R/001)	N/A	27 September 2018
Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH (ES/V/xxxx/IA/031/G)	N/A	26 October 2018