



**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**

**November 2013**

## **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.<br>Wim de Körverstraat 35<br>5831 AN Boxmeer<br>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, 5 and 10 ml and colourless type II glass vials of 50 ml, fitted with halogenated butyl rubber stoppers and aluminium caps. The glass vials and stoppers are in conformity with the Ph.Eur. requirements.

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.