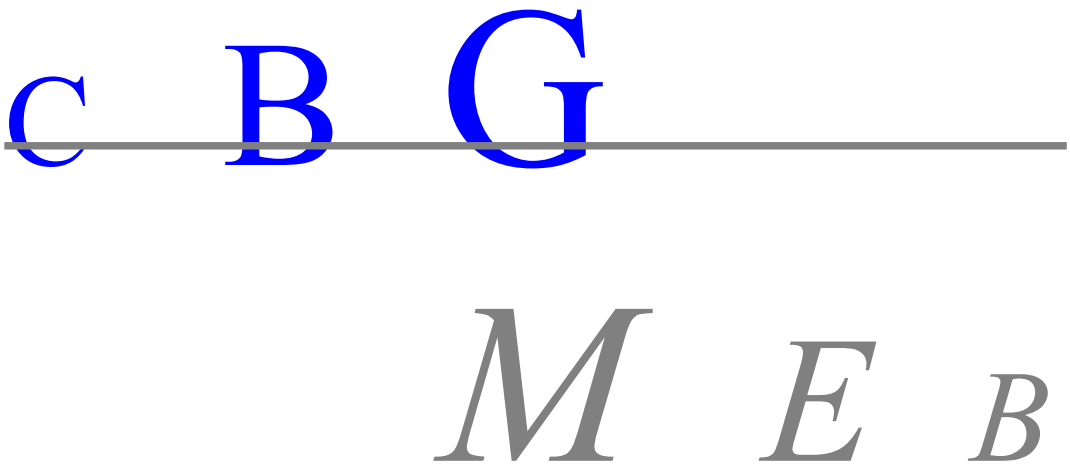

College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Fertigest 0.004 mg/ml solution for injection

Created: November 2019

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0212/001/DC
Name, strength and pharmaceutical form	Fertigest 0.0042 mg/ml solution for injection
Applicant	VETPHARMA ANIMAL HEALTH, S.L. Les Corts, 23 08028 Barcelona| Spain
Active substance(s)	Buserelin acetate
ATC Vetcode	QH01CA90
Target species	Cattle, Horses, Pigs, Rabbits
Indication for use	Cattle: - Treatment of follicular cysts. - Improvement of conception rate in artificial insemination procedures. - Synchronisation of oestrus and ovulation in cyclical cattle, for artificial insemination at a fixed time together with prostaglandin F2α administration. Horse: - Treatment of follicular cysts. - Ovulation induction to synchronise ovulation more closely with mating. Pig: - Ovulation induction after oestrus synchronisation by weaning (sows) or by administering a progestagen (gilts) that can be used as part of a single fixed time artificial insemination programme. Rabbit: - Improving the conception rate. - Ovulation induction postpartum.

MODULE 2

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Vetpharma Animal Health, S.L.	DCP
	Publicly available assessment report

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended
Date of completion of the original decentralised procedure	28 June 2017
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, CZ, DE, ES, HR, HU, IE, PL, PT, 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 warnings and precautions are indicated in the SPC.

The efficacy of the product was demonstrated according to the claims made in the SPC.

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

Fertigest is a generic product in accordance with Article 13(1). The reference product is Receptal, which has been authorized in the Netherlands since 1992-09-08 by Intervet Nederland B.V (REG NL 5327 and REG NL 105583). The initial application for Receptal was assessed before there was a requirement to have a public assessment report.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 0.0042 mg/ml of the active substance buserelin acetate and the sodium chloride, sodium dihydrogen phosphate monohydrate and water for injections.

The container/closure system consists of 20 ml vials composed of clear type I glass sealed with a bromobutyl coated stopper and an aluminium overseal and packaged in an outer carton.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

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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. Sterilisation by filtration is considered suitable.

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 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.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data of only one pilot scale batch 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 site has 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 28 day stability after broaching is based on the demonstration of stability for batches broached and stored 28 days at 2-8°C, protected from light.

Shelf life of the product as packaged for sale: 2 years.
Shelf life of the product after broaching of the primary packaging: 28 days.

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III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmaco-toxicological tests are not required.

The pharmaco-toxicological aspects of this product is/are identical to the reference product.

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 / consumers.

User Safety

The user warnings for the product are the same as for the reference product:

Buserelin has been shown to be foetotoxic in laboratory animals; therefore, pregnant women should not handle the veterinary medicinal product. Women of child-bearing age should administer the product with caution. Avoid eye and skin contact with the product. In case of accidental contact, rinse thoroughly with water. Should skin contact with the product occur, wash the exposed area immediately with soap and water, as GnRH analogues may be absorbed through the skin. Wash hands after use. When administering the product, care should be taken to avoid accidental self-injection by ensuring that animals are suitably restrained and the application needle is shielded until the moment of injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Do not eat, drink or smoke while handling the product.

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

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the initial predicted environmental concentration in soil (PECsoil, initial varies from 0.0005 µg/kg for horses to 0.0043 µg/kg for rabbits) is less than 100 µg/kg.

Withdrawal Periods

As this is a generic product, withdrawal periods are identical to those of the reference product. Therefore, withdrawal periods of zero days for meat in cattle, horses, pigs and rabbits and 0 days for milk (cattle) are justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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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.

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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 (Application number)	**Section updated in Module 3**	**Approval date**
Change in the QPPV and/or QPPV contact details and/or back-up procedure (ES/V/XXXX/IA/024/G)	N/A	5 April 2018

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