ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
KT15 3LS
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Virbagest 4 mg/ml Oral Solution for Pigs

PuAR correct as of 24/07/2018 when RMS was transferred to FR.
Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0237/001/DC
Name, strength and pharmaceutical form	Virbagest 0.4mg/ml Oral Solution for Pigs
Applicant	Virbac S.A.
Active substance	Altrenogest
ATC Vetcode	QG03DX90
Target species	Pigs
Indication for use	For the synchronisation of oestrus in nulliparous mature sows

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies (veterinary) (HMA(v)) website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	27 September 2007
Date product first authorised in the Reference Member State (MRP only)	n/a
Concerned Member States for original procedure	Belgium Czech Republic France Germany Hungary Poland Spain
Concerned Member States for repeat use procedure (1st wave)	Austria Bulgaria Cyprus Greece Ireland Italy The Netherlands Portugal Romania
Concerned Member States for repeat use procedure (2nd wave)	Denmark Poland

I. SCIENTIFIC OVERVIEW

The product was authorised under Article 13 (1) of Directive 2001/82/EC as amended by 2004/28/EC, using the Decentralised Procedure. The UK was the Reference Member State and the procedure ended on 24 September 2007. Two subsequent repeat use procedures, performed under the mutual recognition procedure have followed. Essential similarity was shown with the reference product, Regumate Porcine, which was marketed in the UK since 1985.

The product is indicated for use in pigs, for the synchronisation of oestrus in nulliparous mature sows. The product is provided for oral use as a top dressing for feed at 20 mg altrenogest per animal and per day, for 18 consecutive days. This corresponds to 5 ml of the product per day and per animal for 18 consecutive days.

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 Summary of Product Characteristics (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.

II. QUALITY ASPECTS

A. Composition

The product contains the active substance altrenogest and excipients butylhydroxytoluene (E321), butylhydroxyanisole (E320) and soya-bean oil, refined.

The container/closure system comprises a polyethylene terephthalate bottle with an unremovable plastic shell clipped to the bottle, containing 450 ml or 900 ml of product. The bottle is hermetically closed with child proof screw cap. The particulars of the containers and controls performed are provided and conform to the regulation. The choice of the formulation 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 from 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 altrenogest. Supporting data have been provided in the form of an Active Substance Master File (ASMF). It is considered that the manufacturing process is adequately controlled and the active substance specification has been suitably justified.

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.

All the other substances in the tablets comply with the requirements of the relevant European Pharmacopoeial monographs.

A certificate of conformity is provided for the polyethylene terephthalate stating that it complies with monograph 3.1.15 of the European Pharmacopoeia for “Polyethylene terephthalate for containers for preparations not for parental use”.

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

Not applicable.

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

Stability data on the active substance was discussed in the DMF 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 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.

H. Genetically Modified Organisms

Not applicable

J. Other Information

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 60 days.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, essential similarity with a reference product was confirmed, results of pharmacological tests are not required.

Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users, the environment and consumers when used as directed.

Toxicological Studies

As this is a generic application according to Article 13 (1), of Directive 2001/82/EC as amended and essential similarity with a reference product was confirmed, results of toxicological tests are not required.

Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users, the environment and consumers when used as directed.

User Safety

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, and essential similarity with a reference product was confirmed, user safety data are not required.

Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users, the environment and consumers when used as directed:

- Women who are pregnant, or suspected to be pregnant, should not use the product. Women of childbearing age should handle the product with extreme care. The product should not be handled by persons with known or suspected progesterone-dependent tumours or thrombo-embolic disorders.

- Direct contact with the skin should be avoided. Personal protective clothing (gloves and overalls) must be worn when handling the product. Porous gloves may let this product pass through. Transcutaneous absorption may be even higher when the area is covered by an occlusive material, such as latex or rubber gloves. Accidental spillage on the skin should be washed off immediately with soap and water. Wash hands after treatment and before meals.
- In case of accidental contact with eye, rinse abundantly with water. Get medical attention.
- Effects of overexposure: Repeated accidental absorption could lead to disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy or headache.
- People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product.

Ecotoxicity

The applicant provided a Phase I environmental risk assessment that was considered to be acceptable for demonstration of the environmental safety of the product which showed that no further assessment is required. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, and essential similarity with a reference product was confirmed.

Withdrawal Periods

A withdrawal period of 9 days for meat and offal is justified.

IV CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

The application was made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, and on the basis of being a generic of a reference medicinal product, no further information is required. Essential similarity with the reference medicinal product was confirmed.

Tolerance in the Target Species of Animals

The application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, and on the basis of being a generic of a reference medicinal product, no further information is required. Essential similarity with the reference medicinal product was confirmed by appropriate bioavailability studies.

The product literature and SPC accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

The application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, and on the basis of being a generic of a reference medicinal product, no further information is required. Essential similarity with the reference medicinal product was demonstrated by appropriate bioavailability studies.

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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)