College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Pergoquin 1 mg tablets for horses

Created: September 2019

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0295/001/DC
Name, strength and pharmaceutical form	Pergoquin 1 mg tablets for horses
Applicant	WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG Siemensstr. 14 30827 Garbsen Germany
Active substance(s)	pergolide (as pergolide mesilate)
ATC Vetcode	QN04BC02
Target species	Horses
Indication for use	The veterinary medicinal product is used in the following indications: Symptomatic treatment of clinical signs associated with Pituitary Pars Intermedia Dysfunction (PPID) (Equine Cushing's Disease).

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MODULE 2

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

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	31 July 2019
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Germany, Greece, Hungary, Iceland, Lithuania, Latvia, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden, and United Kingdom.

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 slight reactions observed are indicated in the SPC.
The product is safe for the user 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.

The safety and efficacy aspects of this product are identical to PRASCEND 1 MG TABLETS FOR HORSES, for which a marketing authorization was obtained by Boehringer Ingelheim Vetmedica GmBH under marketing authorization number 401219.00.00 in Germany on August 17, 2009.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The tablet contains 1 mg pergolide (as pergolide mesilate), and the excipients lactose monohydrate, croscarmellose sodium, povidone K30, magnesium stearate, and iron oxide red (E172).
The tablet is cross scored and meant to be broken in halves or quarters.
The products are packed in OPA/Al/PVC blisters, each containing 10 tablets.
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

In vivo bioequivalence between the reference and proposed product has been demonstrated.

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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 from a licensed manufacturing site and in accordance with the European Pharmacopoeia and relevant European guidelines.

The product is manufactured using conventional manufacturing techniques. Suitable validation results on two small production scale batches have been provided. The tests performed during production are described.

C. Control of Starting Materials

The active substance pergolide mesilate, an established active substance described in the European Veterinary Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The CEP procedures have been employed.

The active substance specification, information on the drug substance packaging materials and the excipients specificities have been provided.

None of the starting materials used are affected by the Note for Guidance on TSE/BSE.

D. Control on intermediate products

Not applicable.

E. Control Tests on the Finished Product

The finished product specification controls 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. Photostability data is provided.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from two batch manufactured at the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

The re-test period of 3 years for pergolide mesilate. when stored under the approved conditions is evidenced by the CEP.

Stability data on the finished product have been provided in accordance with applicable VICH guidelines. Based on the stability data provided, the claimed shelf life of 24 months and the claimed in-use shelf life of 3 days can be granted.

G. Other Information

None

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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 pharmacological and toxicological tests are not required.

The pharmacological and toxicological aspects of this product are identical to the reference product.

III.A Safety Testing

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.

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. Phase I: The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

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.

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.
