Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Prasequine 1 mg Tablets for Horses

Date Created: January 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Prasequine 1 mg Tablets for Horses
Applicant	CP Pharma Handelgesellschaft mbH Ostlandring 13 31303 Burgdorf 31303 Germany
Active substance	Pergolide
ATC Vetcode	QN04BC02
Target species	Horses
Indication for use	Symptomatic treatment of clinical signs associated with Pituitary Pars Intermedia Dysfunction (PPID) (Equine Cushing's Disease).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

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

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 conclusion of the procedure	12/01/2023

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to

Prascend 1 mg Tablets for Horses.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains pergolide mesylate and the excipients croscarmellose sodium, iron oxide yellow, lactose monohydrate, magnesium stearate, povidone.

The container/closure system consists of OPA/aluminium/PVC blister packs, with push-through aluminium lidding. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

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

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of dissolving, mixing, drying and sieving.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

II.C. Control of Starting Materials

The active substance is pergolide mesylate, 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 demonstrating compliance with this specification have been provided.

A CEP is provided.

All excipients are described in Ph. Eur. except for yellow iron oxide which complies with EU regulations.

II.C.4. Substances of Biological Origin

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.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 have been provided demonstrating compliance with the specification. Control tests on the finished product are those for: appearance, tablet mass, dissolution, resistance to crushing of tablets, uniformity of dosage units, identification, and assay of pergolide, related substances of pergolide, residual methanol and microbiological quality.

II.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.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life of divided tablets after first opening the immediate packaging: 3 days.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Bioequivalence with the reference product has been established.

Toxicological Studies

Not required as this is a generic application.

User Safety

A user risk assessment was provided 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. Therefore, the following applicant's user recommendations are appropriate:

This veterinary medicinal product may cause eye irritation, an irritating smell, or headache after dividing the tablets. Avoid contact with the eyes and inhalation when handling the tablets. Minimize exposure risks when dividing tablets, e.g., tablets should not be crushed.
In case of contact with skin, wash exposed skin with water. In the event of eye exposure, flush the affected eye immediately with water and seek medical advice. For nasal irritation, move to fresh air and seek for medical attention if breathing difficulty develops.

This product may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to pergolide or other ergot derivatives should avoid contact with the veterinary medicinal product.
This product may cause adverse effects due to decreased prolactin levels, which poses a particular risk to pregnant and lactating women. Pregnant or lactating women should avoid dermal contact or hand-to-mouth contact by wearing gloves when administering the product.

Accidental ingestion, especially by children, may cause adverse reactions. To avoid accidental ingestion, carefully keep the product out of reach and sight of children. Tablet parts should be returned to the open blister space. Blisters should be inserted back into the outer packaging and kept in a safe place. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Do not eat, drink, or smoke when using this product. Wash hands after use.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:
The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Pharmacology

Not required.

Tolerance in the Target Species

Tolerance studies were not required because of the legal basis of the application.

IV.II. Clinical Documentation

Laboratory Trials

Bioequivalence was established in a BE-study.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that the benefit/risk profile of the product is favourable.

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.

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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.

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