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

Gastazole 370 mg/g Oral Paste for Horses

Date Created: October 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Gastazole 370 mg/g Oral Paste for Horses, Oral paste
Applicant	EU Pharmaceuticals Ltd, 37 Geraldine Road, London, SW18 2NR
Active substance	Omeprazole
ATC Vetcode	QA02BC01
Target species	Horses
Indication for use	For treatment of gastric ulcers and the prevention of recurrence of gastric ulcers.

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 8 of VMRs 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	03/07/2024

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to GastroGard 370 mg/g Oral Paste.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains omeprazole and the excipients Ferric Oxide yellow, potassium sorbate, ethanolamine, cassia oil, hyrdrogenated castor oil, calcium stearate, sodium stearate, refined sesame oil, propylene glycol dicapryocaprate.

The container/closure system consists of a white HDPE/LLDPE syringe fitted with a polypropylene plunger with an LDPE contact seal and LDPE cap. 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: sifting, addition of ingredients, mixing, heating and filling.

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines

.

II.C. Control of Starting Materials

The active substance is Omeprazole, 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.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

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, identification of active substance, identification of cinnamon flavour, identification of yellow iron oxide, viscosity, assay, microbiological quality, uniformity and particle size.

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.

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.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 27 months.
Shelf life after first opening the immediate packaging: use immediately

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

As this is a generic application in accordance with Article 8 of VMRs 2013 (Schedule 1, Para 10) as amended, the bioequivalence with a reference product has been demonstrated, results of pharmaco-toxicological tests are not required.

Toxicological Studies

Not applicable due to the legal basis of the product.

User Safety

A user risk assessment was provided in compliance with the relevant guidelines.

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:

- As this product may cause irritation and hypersensitivity reactions, avoid direct contact with skin and eyes. People with known hypersensitivity to omeprazole or any of the excipients should avoid contact with the veterinary medicinal product.
- Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.
- Do not eat or drink when handling and administering the product.
- Wash hands or any exposed skin after use.
- The dosing syringe should be returned to the original packaging and suitably stored to prevent access by children.
- In case of contact with eyes, wash immediately with clean running water and seek medical advice and show the package leaflet or the label to the physician if symptoms persist.
- Persons developing a reaction after contact with the product should avoid handling the product in future.

Environmental Safety

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

Phase I:
The product will be used to treat a small number of animals in a flock or herd and as such environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

As this is a Generic application in accordance with Article 8 of VMRs 2013 (Schedule 1, Para 10) as amended, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required.

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 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.

(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)