IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Gastazole 370 mg/g oral paste for horses

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Gastazole 370 mg/g oral paste for horse
Active substance(s)	Omeprazole
Applicant	Chanelle Pharmaceuticals Manufacturing Limited Loughrea Co.Galway
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of Authorisation	15th May 2020
Target species	Horses
Indication for use	For treatment of gastric ulcers and the prevention of recurrence of gastric ulcers
ATCvet code	QA02BC01

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

It has been shown that the product can be safely used in the target species.

The product is safe for the user, consumer and 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 benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 370 mg/g of omeprazole as the active substance and the excipients hydrogenated castor oil, potassium sorbate (E202), ferric oxide yellow (E172), ethanolamine, cassia oil, calcium stearate, sodium stearate, sesame oil, refined and propylene glycol dicaprylocaprate.

The container/closure system is an opaque white pre-filled oral syringe containing 7.57 g of paste.

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 at licensed manufacturing sites.
Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

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 has been provided.

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.

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 has 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 has 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 has 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
Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

The application was made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). The reference product cited by the applicant is GastroGard 37% w/w Oral Paste for Horses marketed by Boehringer Ingelheim Vetmedica GmbH.

III.A Safety Testing

Pharmacological Studies
The Applicant conducted an *in-vivo* bioequivalence study comparing the pharmacokinetic profile of the product with that of the reference product in horses when administered by the oral route. It is accepted on the basis of this study that the product and reference product exhibit comparable rates and extent of absorption following oral administration at a dose rate of 4 mg omeprazole/kg bodyweight to horses and can be considered bioequivalent.

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been demonstrated, results of other pharmacological tests are not required.

Toxicological studies
As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

User safety
The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the risk to the user associated with this product is identical to that of 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.

Environmental Risk Assessment
The Applicant has provided an environmental impact assessment as required.
Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

Consumer safety
As this is a generic application under Article 13(1) and as bioequivalence with a reference product is accepted, studies investigating the depletion of residues are not required.
The active substance omeprazole is included in table 1 of the Commission Regulation (EU) No. 37/2010 with "No MRL required" status.
The proposed withdrawal periods are identical to those approved for the reference product in the RMS and are considered adequate to ensure consumer safety.

IV. CLINICAL ASSESSMENT

See Part III.

As this is a generic application under Article 13(1) and as bioequivalence with a reference product is accepted, efficacy studies are not required.

The efficacy claims for this product are expected to be equivalent to those of the reference product. In addition, it is considered that the risk to the target species will be similar for both the test and the reference products.

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 for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI. 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 HPRA website.

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.

Changes:
None.