Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Gastrogard Sport 370 mg/g Oral Paste for Horses

Date Created: August 2018

PuAR correct as of 27/02/2019 when RMS was transferred to IT.
Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0622/001/DC
Name, strength and pharmaceutical form	Gastrogard Sport 370 mg/g Oral Paste for Horses
Applicant	Merial Animal Health Limited PO Box 327 Sandringham House Harlow Business Park Harlow Essex CM19 5TG
Active substance(s)	Omeprazole
ATC Vetcode	QA02BC01
Target species	Horses
Indication for use	For the treatment and prevention 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	Informed Consent application in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Date of conclusion of the decentralised procedure	09/08/2018
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	Italy

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to GastroGard 370 mg/g Oral paste.
The initial application for GastroGard 370 mg/g Oral paste was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. 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.

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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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