Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Omeproshield 370 mg/g Oral Paste for Horses

Date Created: 28 April 2015

PuAR correct as of 26/06/2018 when RMS was transferred to IE.
Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0527/001/DC
Name, strength and pharmaceutical form	Omeproshield 370 mg/g Oral Paste for Horses
Applicant	Merial Animal Health Ltd PO Box 327 Sandringham House Harlow Business Park Harlow Essex CM19 5TG
Active substance(s)	Omeprazole
ATC Vetcode	QA02 BC01
Target species	Horses
Indication for use	For treatment and prevention of gastric ulcers.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed consent application in accordance with Article 13c of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	22 January 2015
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	Austria, Belgium, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Spain

I. SCIENTIFIC OVERVIEW

The quality, safety and efficacy aspects of this product are identical to Gastrogard 37% w/w Oral Paste for Horses. The initial application for Gastrogard 37% w/w Oral Paste for Horses was assessed before there was a requirement to have a public assessment report. However, the product has since undergone a repeat use procedure and a public assessment report is available online.

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(s) is favourable

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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 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.

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