IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Omeproshield 370 mg/g oral paste for horses

PRODUCT SUMMARY

EU Procedure Number	IE/V/0488/001 (formerly UK/V/ 0527/001)
Name, Strength, Pharmaceutical Form	Omeproshield 370 mg/g oral paste for horses
Active Substances(s)	Omeprazole
Applicant	Boehringer Ingelheim Vetmedica GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany
Legal Basis of Application	Informed consent application (Article 13c of Directive No 2001/82/EC)
Target Species	Horses
Indication For Use	For treatment and prevention of gastric ulcers.
ATC Code	QA02BC01
Date of completion of the original decentralised procedure	22 January 2015 (UK) 13 March 2015 (IE)
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	Austria, Belgium, France, Germany, Ireland (now

	RMS), Italy, Luxembourg, Netherlands, Spain UK added via RMS change

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

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.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

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.