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PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR VETERINARY USE

1 PRODUCT SUMMARY

Name, strength and pharmaceutical form	Telmin 200 mg/ml Oral Paste
Active substance(s)	Mebendazole
Marketing authorisation holder	Elanco Animal Health, Eli Lilly and Company Limited
Marketing authorisation number	VPA 10047/044/001
Legal basis of application	Variation application in accordance with Article 12.3 of Directive 2001/82/EC, as amended.
Date of authorisation	01/10/1989
Indication and target species	An oral broad spectrum anthelmintic for the treatment of helminthiasis in the horse and donkey
Method of sale and supply	LM
Additional supply restrictions	None

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

2 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 HPRA leading to the approval of the product for marketing in Ireland.

2.1 Scientific Overview

The initial application for Telmin 200 mg/ml Oral Paste was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available. Please refer to section 2.6 for significant post-approval changes which are important for the quality, safety and efficacy of the product.

2.2 Quality Aspects

See section 2.1

2.3 Safety and residues assessment (pharmaco-toxicological)

See section 2.1.

2.4 Clinical Assessment

See section 2.1.

2.5 Overall conclusion and benefit-risk assessment

On the basis of the original data submitted, the HPRA considered that Telmin 200mg/ml Oral Paste demonstrated adequate evidence of efficacy for the approved indication(s) as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

2.6 Post-authorisation assessments

The SPC and package leaflet are updated on a continuous basis to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA's website.

09/09/08. The HPRA received a variation application to update the SPC and product literature in line with EMEA guidelines. The update included a change to the product name from Telmin Paste to Telmin 200mg/ml Oral Paste. Updates concerning statements to be included in SPCs of anthelmintic products in respect of reducing anthelmintic resistance were also included. This variation procedure was processed under a work-sharing initiative with the UK VMD. The SPC and product literature were updated and the procedure was completed in January 2009.