



Post Authorisation Assessments

Dormazolam 5 mg/ml Solution for Injection for Horses

Vm 50406/3006

•	04 March 2024	Change of legal entity from Le Vet. Beheer B.V., Wilgenweg 7, 3421 TV Oudewater, The Netherlands to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
•	04 January 2024	SRP to add 8 member states.
•	14 September 2023	One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.
•	10 March 2023	Submission of an updated Ph. Eur. certificate of suitability.
•	02 March 2022	Admin Renewal
•	04 April 2019	Change of RMS from UK to PT.
•	21 November 2018	Changes to the labelling and package leaflet. Change in distributor details. From Le Vet. Beheer B.V., Wilgenweg 7, 3421 TV Oudewater, The Netherlands to Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom.
•	09 October 2018	New mutual recognition procedure (MRP) – UK as RMS