Veterinary Medicines Directorate

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Post Authorisation Assessments

Dormazolam 5 mg/ml Solution for Injection for Horses

Vm 50406/5009

01 May 2025	Submission of updated mock ups.
19 January 2025	Changes in relation to MR/SR procedures: - Adaptation of the Product Information for the original Concerned Member States after a SRP. One-off alignment of the product information with version 3 of the national QRD template.
23 November 2024	Deletion of a Ph. Eur. CEP for an active substance.
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.
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 February 2023	Updated certificate of suitability from an already approved manufacturer.
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