Veterinary Medicines Directorate

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Post Authorisation Assessments

Pardale-V 400 mg/9 mg Tablets

Vm 50406/5027

09 December 2025	One-off alignment of the product information with version 9.0 of the QRD templates.
02 December 2025	Addition of a quality control testing site.
24 November 2025	Tightening of specification limits of an excipient. Minor changes to an approved test procedure for an excipient.
17 October 2025	Addition of a manufacturer responsible for batch release.
28 August 2025	Change in the specification parameters and/or limits of the finished product.
03 April 2025	Submission of a CEP for the manufacture of an active substance.
13 February 2025	Change in legal entity of MA holder from Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
04 March 2024	Change in the specification parameters and limits of the finished product.
20 February 2023	Change to in-process tests or limits applied during the manufacture of the finished product
23 December 2022	Updated certificate of suitability from an already approved manufacturer.
05 October 2022	Change in specification parameters of the finished product
06 July 2022	Editorial changes to Quality section of the dossier.
14 June 2022	Updated certificate of suitability for an active substance.
09 December 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
29 January 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
22 June 2020	Minor change in the manufacturing process of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Minor adjustments of the quantitative composition of the finished product with respect to excipients.
13 December 2019	Change of the legal category from NFA-VPS to POM-V.
30 July 2019	Addition of new tests and limits applied during the manufacture of the finished product.
12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
04 October 2017	Changes to the labelling and/or package leaflet.
26 January 2016	Change in the address of the marketing authorisation holder.
16 October 2012	Grouped variation to update a Certificate of Suitability, and also

	to submit a new Certificate of Suitability.
06 January 2011	Variation to change a Distributor.
21 December 2010	Variation to change the Active Substance Manufacturer.
10 October 2007	Renewal.
15 August 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from P to NFA-VPS.
10 May 2007	Variation to change the Marketing Authorisation Holder.
30 April 2003	Renewal.
11 April 2003	Change of Manufacturer of Active Substance.
29 September 1998	Renewal.
18 November 1997	Extension of shelf life.