

Post Authorisation Assessments

Vectin Horse Oral Paste 18.7 mg/g Vm 50146/4006

•	March 2024	Deletion of a CEP for the manufacture of an active substance. (NI) Deletion of a CEP for the manufacture of an active substance. (NI)
•	March 2024	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance. (NI)
•	March 2024	Deletion of a CEP for the manufacture of an active substance. (GB) Deletion of a CEP for the manufacture of an active substance. (GB)
•	13 April 2024	Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile active substance. (NI)
•	28 September 2021	Change in the fill volume of the finished product.
•	30 March 2021	Minor changes in the SPC, whereby amendments are made to typographical errors in Section 4.5 and 4.7 of the SPC.
•	18 March 2021	Replacement of a secondary packaging site of the finished product.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	27 July 2020	Change in distributor details from Intervet UK Ltd, Walton Manor, Walton, Milton Keynes, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ.
•	25 September 2019	Change in the invented name of the veterinary medicinal product from Diapec P Gel to Bimectin Paste in Germany only.
•	15 August 2019	Change in the name address of the manufacturer of the finished product. Change in the name and address of a manufacturer of the finished product, also responsible for batch release. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 October 2018	Change of MAH, from Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
•	12 March 2018	Change in RMS from UK to IE.
•	12 January 2016	Submission of an updated certificate of suitability.

•	18 October 2012	Submission of a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	29 March 2012	Grouped variation concerning the submission of updated European Pharmacopoeia Certificates of Suitability for already approved active substance manufacturers.
•	03 October 2008	Renewal (UK as RMS).
•	19 September 2008	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	20 July 2006	Extension of the finished product shelf life.
•	16 December 2005	Addition of a site for assembly only.
•	22 September 2005	Change of distributor.
•	17 August 2005	Variation to harmonise the SPC between the UK and IE.
•	17 August 2005	Repeat use procedure.
•	23 July 2004	Variation to change the name of the veterinary medicinal product in PT only.
•	09 October 2003	New EUDE (UK as RMS)
•	19 June 2002	New Marketing Authorisation.