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Post Authorisation Assessments

Vectin Horse Oral Paste 18.7 mg/g

Vm 50146/4006

•	23 April 2024	Deletion of a CEP for the manufacture of an active
		substance. (NI)
		Deletion of a CEP for the manufacture of an active
	22 Amril 2024	substance. (NI)
•	23 April 2024	Submission of a new Ph. Eur. CEP from a new
	22 April 2024	manufacturer for a non-sterile active substance. (NI)
•	23 April 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
•	13 April 2024	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
•	30 Wardi 2021	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
	TO Maron 2021	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
	4.5.4.	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.
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•	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.