Veterinary Medicines Directorate

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Post Authorisation Assessments

Bimectin Horse Oral Paste 1.87% w/w

Vm 50146/4036

•	22 November 2021	Change in the fill weight / 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.
•	23 July 2019	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	26 October 2018	Changes to an existing pharmacovigilance system as described in the DDPS. 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.
•	06 January 2016	Submission of an updated certificate of suitability.
•	23 August 2012	Addition of a manufacturer of the active substance Submission of a new Ph. Eur. Certificate of Suitability for an active substance
•	07 February 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	15 June 2011	Submission of an updated Ph. Eur. Certificate of Suitability for an excipient
•	04 February 2009	Renewal
•	01 October 2008	Change of legal category from PML to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation
•	12 September 2008	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance from an already approved manufacturer
•	16 November 2006	Increase of shelf life from 18 months to 2 years
•	10 December 2005	Addition of a secondary site of assembly
•	20 August 2004	Change of product name from ‘Maximec’ to ‘Bimectin Horse Oral Paste 1.87% w/w’
•	04 June 2004	Change of distributor