Veterinary Medicines Directorate

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Post Authorisation Assessments

Vitamin B1 10% w/v Solution for Injection

Vm 50146/4029

•	21 October 2024	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State.
•	18 September 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	01 August 2023	Change in the manufacturing process of the finished product. Change in immediate packaging of the finished product: - Change in type of container or addition of a new container.
•	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.
•	25 October 2018	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of MAH, from Bimeda Chemicals Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
•	15 October 2018	Change in distributor details. From Bimeda Chemicals Ltd, Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda ®, Cross Vetpharm Group UK Ltd., Unit 2, Bryn Cefni, Llangefni, Anglesey, LL77 7XA, United Kingdom
•	03 July 2013	Submission of an updated European Pharmacopoeia Certificate of Suitability from a currently approved active substance manufacturer.
•	17 May 2012	Grouped variation to change the finished product specification.
•	28 July 2010	Grouped variation to change the name of an active substance manufacturer via the submission of an updated European Pharmacopoeia Certificate of Suitability from a currently approved active substance manufacturer.
•	08 January 2009	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	10 September 2008	Variation to the formulation of the finished product.

•	17 January 2008	Renewal.
•	12 December 2003	Renewal.
•	22 May 2003	Addition of an assembler of dosage form.
•	16 November 2001	Addition of a dosage form manufacturer.
•	26 July 1999	Renewal.