



Post Authorisation Assessments

Vectocert 1.25% w/v Pour on Solution for Sheep Vm 50146/4037

•	20 October 2023	Change to the in-process controls applied during the manufacture of the finished product.
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•	18 November 2022	Replacement of a quality testing site.
•	26 April 2022	Tightening of specification limits of the immediate packaging of the finished product. Tightening of specification limits of the immediate packaging of the finished product. Tightening of specification limits of the immediate packaging of the finished product.
•	27 April 2021	Change in distributor details from Downland Marketing Ltd., 15 Victoria Place, Carlisle, CA1 1EW to Downland Marketing Ltd., Main Mill, Warwick Mill Business Centre, Warwick Bridge, Carlisle, CA4 8RR.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	24 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.
•	23 July 2018	Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product.
•	27 November 2017	Minor changes to an approved test procedure of the finished product. Deletion of a non-significant specification parameter of the finished product.
•	23 March 2017	Renewal - National
•	07 January 2016	Changes in the dimensions of the immediate packaging. Addition of a new specification parameter of the immediate packaging of the finished product.
•	20 May 2015	Changes in the specification parameters of an excipient.

•	14 April 2014	Change to the test procedure for the finished product. Change to the specification parameters of an excipient.
•	20 June 2013	Change in test procedure to identify active substance in finished product.
•	06 June 2013	Introduce and manufacturing hold time and a filling hold time.
•	06 June 2013	Change in batch size.