Veterinary Medicines Directorate

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Post Authorisation Assessments

Ectofly 12.5 mg/ml Pour-on Solution for Sheep

Vm 50146/4017

•	17 November 2023	Deletion of an in-process control applied during the manufacture of the finished product. (NI)
•	17 November 2023	Deletion of an in-process control applied during the manufacture of the finished product. (GB)
•	17 November 2023	Change to the in-process controls applied during the manufacture of the finished product. (NI)
•	17 November 2023	Change to the in-process controls applied during the manufacture of the finished product. (GB)
•	06 July 2023	Tightening of specification limits of the immediate packaging of the finished product.
•	06 July 2023	Change to importer, batch control arrangements and quality testing for a finished product.
•	23 December 2022	Replacement of a quality testing site.
•	21 December 2022	Change in the specification parameters or limits of the immediate packaging of the finished product:– tightening of specification limits. Change in the specification parameters or limits of the immediate packaging of the finished product:– tightening of specification limits. Change in the specification parameters or limits of the immediate packaging of the finished product:– tightening of specification limits.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	20 September 2019	Change in the name (only) of quality control testing site. 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.
•	19 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.
•	09 October 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.
•	06 July 2018	Change in RMS from UK to FR.
•	29 December 2017	Minor changes to an approved test procedure of the finished product.

		Deletion of a non-significant specification parameter of the finished product.
•	25 October 2017	Change in the number of units (e.g. tablets, ampoules, etc.) in a pack outside the range of the currently approved pack sizes of the finished product.
•	02 May 2017	Changes to the labelling and package leaflet
•	27 July 2016	Renewal – UK as RMS
•	22 March 2016	Change in the dimensions of the immediate packaging container. Addition of a new specification parameter for the immediate packaging of the finished product.
•	19 June 2015	Changes to the specification parameters of an excipient.
•	05 June 2015	Changes to the withdrawal period.
•	10 April 2014	Change in test procedure for the finished product. Change in specification parameters of an excipient.
•	28 June 2013	Change in method for identification and quantification of the active substance.
•	07 May 2013	To change the manufacturing process of the finished product and to increase the batch size of the finished product.