Veterinary Medicines Directorate

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Post Authorisation Assessments

Betafuse 1 mg/g + 5 mg/g Gel for Dogs

Vm 02000/4404

•	11 May 2024	Submission of an updated CEP for the manufacture of an active substance. (NI)
•	08 March 2024	CEP updated for the manufacture of an active substance.
•	23 November 2023	Introduction of a summary of the PSMF. (NI)
•	17 November 2023	Editorial changes relating to updating the method of analysis of the finished product.
•	03 February 2023	Change in dimensions of the immediate packaging of the finished product.
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, BT35 6QQ, Co. Down, Northern Ireland.
•	22 September 2022	Change in dimensions of the immediate packaging of the finished product.
•	27 August 2021	Renewal – UK as CMS.
•	27 October 2020	Addition of a secondary packaging site of the finished product.
•	11 September 2019	Minor changes to an approved test procedure of the finished product. Tightening of specification limits of an excipient.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	26 July 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	19 June 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	20 November 2018	Change in RMS from UK to IE.
•	10 April 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.