Veterinary Medicines Directorate

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Post Authorisation Assessments

Moxiclear 400 mg + 100 mg Spot-on Solution for Very Large Dogs

Vm 02000/4440

•	March 2024	Additional site of batch control for the finished product. (NI) Minor changes to an approved test procedure for the finished product. (NI)
•	22 December 2023	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	03 August 2023	Change to batch control arrangements for the finished product. (GB) Minor change to an approved test procedure of the finished product. (GB)
•	26 June 2023	Submission of a new or updated Ph. Eur. certificate of suitability. (GB)
•	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, Co Down, BT35 6QQ, Northern Ireland.
•	29 July 2022	Unlimited renewal.
•	13 May 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	27 May 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 September 2019	Minor change in the manufacturing process of the finished product.
•	22 August 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	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.
•	27 June 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.

•	22 August 2018	Minor changes to SPC/QRD