

Post Authorisation Assessments

Moxiclear 40 mg + 10 mg Spot-on Solution for Small Dogs Vm 02000/4437

•	18 April 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
	26 June 2023	finished product. (GB)
•		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
	07 Marc 0000	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
	27 June 2019	DDPS. 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
---	----------------	--------------------------