Veterinary Medicines Directorate

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Post Authorisation Assessments

Noromectin 0.08% w/v Drench Oral Solution

Vm 02000/4184

•	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.
•	06 August 2022	To introduce a new 5 Litre BackPack with minor dimensional changes.
•	12 August 2022	Deletion of a non-significant specification parameter for a raw material.
•	11 August 2022	Deletion of a non-significant specification parameter for a raw material.
•	03 August 2022	Deletion of certificates of suitability for an active substance.
•	05 July 2022	Change in dimensions of polyethylene back pack. Change in dimensions of polyethylene back pack. Addition of tamper evident cap.
•	19 January 2022	Minor changes to an approved test procedure of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	18 May 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	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.
•	04 October 2016	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.
•	27 July 2015	Submission of an updated certificate of suitability from an already approved manufacturer.
•	15 June 2010	Corrections to section 4.9 of the SPC.
•	20 September 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	07 February 2007	Transfer of legal category from POM to POM-VPS.
•	10 January 2007	Addition of an Active Substance Manufacturer.
•	01 February 2006	Renewal.

•	25 October 2005	Variation to change the Target Species.
•	12 October 2005	Addition of an Assembler.
•	26 November 2004	Extension of finished product shelf life.
•	25 June 2003	Variation to change the target species.
•	14 December 2000	Change to Safety Warnings.
•	25 May 2000	New Marketing Authorisation