Veterinary Medicines Directorate

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Post Authorisation Assessments

Noromectin 1% w/v Multi Injection Solution for Injection

Vm 02000/4174

•	25 August 2023	Deletion of a non-significant specification method. Editorial changes to Part II of the dossier. Minor changes to an approved test procedure for the finished product.
•	03 March 2023	Change in any part of the primary packaging material not in contact with the finished product formulation.
•	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.
•	12 August 2022	Deletion of certificates of suitability for an active substance.
•	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.
•	14 May 2018	Change of specification(s) of a former non Pharmacopoeial excipient to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Change of specification(s) of a former non Pharmacopoeial excipient to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
•	28 February 2018	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	07 February 2017	Update of the test procedure to comply with the updated general Ph. Eur monograph. Tightening of specification limits of the finished product Deletion of a non-significant specification parameter of the finished product.
•	17 August 2015	Submission of an updated certificate of suitability.
•	13 December 2012	Grouped variation concerning the addition of new Ph. Eur. Certificates of Suitability from already approved manufacturers. Addition of an Active Substance Manufacturer.
•	03 April 2012	Variation to change the address of a Distributor.
•	15 December 2009	Variation to extend the withdrawal period in cattle.
•	28 January 2009	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.

•	07 February 2007	Variation to transfer the legal category to POM-VPS.
•	25 January 2006	Renewal.
•	19 October 2005	Addition of an Active Substance Manufacturer.
•	12 October 2005	Variation concerning the addition of an Assembler.
•	11 February 2004	Change to shelf life specification limit.
•	29 August 2002	Variation to change product name.
•	07 January 2002	Line extension to add a target species.
•	06 July 2001	Manufacturer of Active Substance.
•	08 February 2000	Variation concerning the addition of a container size.
•	20 October 1999	New Marketing Authorisation.