Veterinary Medicines Directorate

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Post Authorisation Assessments

Noromectin 1.87% Oral Paste for Horses

Vm 02000/5009

26 August 2025	Submission of updated mock ups.
23 June 2025	Minor changes to the package leaflet.
01 May 2025	One-off alignment of the product information with version 9.0* of the QRD templates.
November 2023	Change in pack size of the finished product: - Change in the number of units in a pack outside the range of the currently approved pack sizes.
15 March 2023	Deletion of CEPs for an active substance
03 February 2023	Replacement of a secondary packaging site of a 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, Co Down, BT35 6QQ, Northern Ireland.
28 September 2022	Replacement of a secondary packaging site of a finished product.
27 October 2020	Addition of a secondary packaging site of the finished product.
23 August 2019	Change in shape or dimensions of the container or closure (immediate packaging). Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Deletion of a non-significant specification parameter of the finished product. Changes to a test procedure for the finished product. Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers. Replacement of a specification parameter with its corresponding test method of the finished product. Replacement of a specification parameter with its corresponding test method of the finished product. Change in the specification limits of the finished product. Quantitative changes to the excipients.
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.
12 July 2019	Addition of a manufacturer responsible for batch release of the finished product.
12 August 2015	Submission of an updated certificate of suitability
28 November 2014	Update to the DDPS.

14 December 2012	Grouped variation concerning the submission of Ph. Eur. Certificates of Suitability. Addition of an Active Substance Manufacturer.
21 March 2012	Variation to change the address of a Distributor.
17 December 2010	Deletion of a specification parameter.
26 February 2008	Addition of an Active Substance Manufacturer.
25 May 2007	Renewal.
07 February 2007	Transfer of the legal category to POM-VPS.
12 July 2006	Variation to change the pack size of the finished product.
21 June 2006	Variation to change the shelf life of the finished product.
13 December 2004	Variation to change product name.
11 April 2003	Addition of a pack size.
04 December 2002	New EUDE Marketing Authorisation.