Veterinary Medicines Directorate

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Post Authorisation Assessments

Norodine Equine Oral Paste

Vm 02000/4098

•	17 April 2023	Deletion of two Ph. Eur CEP for an active substance. Addition of a new Ph. Eur CEP from a new manufacturer for a non-sterile active substance.
•	24 February 2023	Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter in the specification parameters or limits of the 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.
•	17 September 2020	Addition of a secondary packaging site of the finished product.
•	02 April 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	10 February 2020	Update of the test procedure to comply with the updated general Ph. Eur monograph. Minor change in the manufacturing process of the finished product. Replacement of an excipient with a comparable excipient. Replacement of an excipient with a comparable excipient.
•	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.
•	05 September 2018	Increase in batch size (400kg) of the finished product.
•	14 November 2016	Submission of an updated certificate of suitability.
•	17 July 2013	Submission of updated EDQM certificates of suitability for already approved active substance manufacturers. Submission of an EDQM certificate of suitability from a new active substance manufacturer.
•	29 May 2012	Change of address of the distributor.
•	05 November 2008	Changes to the SPC and product literature to bring them into line with new legislation.
•	14 October 2008	Deletion of an active substance manufacturer.
•	08 May 2008	Submission of an updated European Pharmacopoeia

		Certificate of Suitability for an already approved active substance manufacturer.
•	03 January 2008	Addition of an active substance manufacturer.
•	28 December 2007	Addition of an active substance manufacturer.
•	09 August 2007	Renewal.
•	21 February 2007	Addition of a manufacturer/assembler.
•	20 February 2007	Variation to change the legal category from POM to POM-V.
•	02 November 2005	Addition of an assembler.
•	11 November 2004	Horse Passport Variation.
•	09 May 2003	Renewal.
•	12 September 2000	Change to the active substance manufacturer.
•	19 October 1999	Addition of an active substance manufacturer.
•	30 April 1998	Addition of an active substance manufacturer.
•	04 March 1998	Renewal.
•	10 October 1996	Revised manufacturer of active substance.