Veterinary Medicines Directorate

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Post Authorisation Assessments

Molemec Paste for Horses 18.7 mg/g Oral Paste

Vm 61700/3013

28 November 2025	Change in legal entity of MA holder in NI only from Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom to Boehringer Ingelheim Vetmedica GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.
04 August 2025	Change in the test procedure of the finished product.
04 March 2025	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
07 January 2025	Change of Distributor address only from Mole Valley Farmers Ltd., Station Road, South Molton, North Devon, EX36 3BH to Mole Valley Farmers Ltd., Exmoor House, Lime Way, Pathfields Business Park,South Molton, Devon, EX36 3LH. Approval of mock ups.
23 August 2023	Change in contact details of the batch control site.
11 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
10 August 2022	Change in address of manufacturer of the finished product.
14 April 2022	Addition of a new container for the finished product. Change in the fill weight of the finished product. Change in the fill weight of the finished product. Change in shape or dimensions of the container or closure (immediate packaging).
09 June 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
28 May 2020	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
07 February 2019	Change in the name of the manufacturer of the finished product.
02 January 2019	Change in the manufacturing process of the active substance.
01 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
28 February 2017	Change to part of the (primary) packaging material not in contact with the finished product formulation.
27 July 2016	Renewal
04 November 2015	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
29 October 2015	Submission of an updated certificate of suitability for a

	manufacturer of an active substance.
20 October 2015	Submission of an updated certificate of suitability for a manufacturer of an active substance.
07 June 2013	Change in manufacturing process of the finished product. Change in batch size of finished product. Change in specification parameters of the finished product.