Veterinary Medicines Directorate

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Post Authorisation Assessments

Molemec Plus Paste for Horses 15.5 mg/g / 77.5 mg/g Oral Paste

Vm 08327/4252

•	24 November 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer. (GB)
•	10 August 2023	Added in Adverse Events sections of the SPC and QRD: 'Digestive discomfort has been observed in very rare cases based on post-marketing surveillance data.'
•	12 July 2023	Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range.
•	06 April 2023	Changes in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	28 February 2023	Submission of a new certificate of suitability from a new manufacturer.
•	27 January 2023	Change in address of manufacturer of the finished product.
•	27 January 2023	Change in address of manufacturer of the finished product.
•	25 August 2022	Submission of a new certificate of suitability from a new manufacturer.
•	16 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).
•	21 September 2020	Minor change in the manufacturing process of the finished product.
•	28 May 2020	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	29 January 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	07 February 2019	Change in the name of the manufacturer of the finished product.
•	16 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	20 June 2018	Change in RMS from UK to FR.

•	01 March 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	06 April 2017	Change to part of the packaging material not in contact with the finished product formulation.
•	09 August 2016	Renewal – UK as RMS
•	08 December 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
•	11 June 2015	Submission of an updated Ph. Eur. Certificate of Suitability.
•	08 May 2015	Submission of an updated Ph. Eur. Certificate of Suitability.
•	31 January 2013	New copycat/Informed consent, Mutual Recognition Procedure.
•	18 January 2013	Addition of a supplier of packaging components or devices. Change to the design of the syringe.
•	30 November 2012	Minor changes to the manufacturing process, submission of a updated certificates of suitability for the active substance, deletion of a manufacturing site.
•	13 October 2011	Change in the specification parameters for the active substance.
•	12 October 2011	Change in the specification parameters for the active substance.