Veterinary Medicines Directorate

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Post Authorisation Assessments

Molemec Super Solution for Injection for Cattle

Vm 08327/4253

•	05 October 2023	Minor change in the manufacturing process of the finished product.
•	06 April 2023	Changes in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	18 August 2022	Change in address of manufacturer of the finished product.
•	12 July 2022	Change in the manufacturer of the active substance where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
•	30 December 2021	Change in the name and/or address of a manufacturer of the finished product.
•	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.
•	31 July 2019	Change in shape or dimensions of the container or closure (immediate packaging).
•	03 May 2019	Minor change in the manufacturing process of the finished product.
•	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.
•	30 October 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.
•	14 March 2018	Renewal - National
•	05 September 2016	Changes to advice on dosing regimen and minor changes to wording of SPC.
•	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 November 2014	Deletion of two manufacturing sites.
•	29 July 2014	Change in manufacturer of a starting material used in the manufacturing process of the active substance.
•	14 July 2014	Change to the manufacturing process of the finished product.
•	13 May 2014	Change in the batch size of the active substance.
•	12 September 2013	Deletion of a manufacturing site of the finished product.
•	03 September 2013	Addition of a site responsible for batch control.