



Post Authorisation Assessments

Molemec Injection for Cattle and Sheep 10 mg/ml Solution for Injection Vm 08327/4251

•	03 October 2023	Minor change in the manufacturing process of the finished product.
•	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.
•	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.
•	28 August 2019	Change in shape or dimensions of the container or closure (immediate packaging).
•	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.
•	20 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.
•	15 July 2014	Change to the manufacturing process of the finished product.
•	03 September 2013	Addition of a batch control testing site.
•	26 June 2012	Deletion of an active substance supplier. Submission of updated EDQM certificates of suitability for two active substance suppliers.
•	27 March 2012	Variation to change the source of glycerol formal to

		vegetable origin.
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