



Post Authorisation Assessments

Molemec Drench for Sheep 0.8 mg/ml Oral Solution Vm 08327/4249

•	11 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	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.
•	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.
•	13 June 2017	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	29 November 2016	Renewal.
•	13 July 2016	The proposed alternative caps with new bottle seals and cap liners will replace the current caps, seals and liners manufactured once the stock of the current supply has been exhausted.
•	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.
•	26 June 2012	Deletion of a manufacturing site for the active substance. Submission of updated Ph. Eur. Certificates of Suitability.