



Post Authorisation Assessments

Molemec Pour-on for Cattle 5 mg/ml Pour-on Solution Vm 08327/4247

•	06 April 2023	Changes in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	20 December 2022	Minor changes to an approved test procedure for active substance.
•	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.
•	15 February 2017	Change in storage conditions of the finished product.
•	25 January 2017	Tightening of specification limits of the immediate packaging of the finished product. Change in specification parameters of the immediate packaging of the finished product.
•	02 June 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.
•	25 June 2015	Change to the dosing device.
•	09 January 2015	Change to the immediate packaging of the finished product.
•	26 June 2012	Deletion of a manufacturing site for an active substance. Submission of two updated Ph. Eur. Certificates of Suitability for an active substance.