



Post Authorisation Assessments

EpriMole 5 mg/ml Pour-on Solution for Cattle

Vm 08327/4281

•	15 December 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI) Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	01 February 2023	Deletion of a test procedure used for identification of a solvent used in the manufacturing process of the active substance. Minor changes to a test procedure used for the identification of a solvent used in the manufacturing process of the active substance.
•	13 January 2023	Addition of an alternate method (HPLC) to the current method (TLC) for In-Process control applied during the manufacture of the active substance.
•	03 November 2022	Addition of an alternate method (HPLC) to the current method (TLC) for In-Process control applied during the manufacture of the active substance.
•	09 August 2022	Deletion of a test procedure used for identification of a solvent used in the manufacturing process of the active substance. Minor changes to a test procedure used for the identification of a solvent used in the manufacturing process of the active substance.
•	22 February 2022	Change in the name and address of a manufacturer used in the manufacture of the active substance.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	03 September 2021	Renewal – UK as CMS.
•	28 May 2020	Change in the name 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.
•	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.
•	26 June 2018	Change in RMS from UK to IE.

•	05 January 2018	Deletion of manufacturing site for an active substance.
•	30 August 2017	Change in the address of the marketing authorisation holder in BE, DK, FI, LU, NO, PT, ES & SE only.
•	07 June 2017	Addition of a new in-process test and limit applied during the manufacture of the active substance. Minor change in the manufacturing process of the active substance.
•	15 May 2017	Change to part of the (primary) packaging material not in contact with the finished product formulation. 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. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Change in shape or dimensions of the container or closure (immediate packaging).