



Post Authorisation Assessments

Fendicam 20 mg/ml Solution for Injection for Cattle, Pigs and Horses Vm 08749/4090

•	18 April 2024	Updated CEP submitted for the manufacture of an active substance.
•	21 June 2023	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: – to reflect compliance with the Ph. Eur. by removing reference to the internal test method and test method number.
•	16 May 2022	Updates to the ASMF.
•	11 February 2022	Deletion of manufacturing site for finished product.
•	10 September 2021	National renewal.
•	23 June 2020	Addition of a manufacturer responsible for batch release including batch control/testing. Minor change of the manufacturing process of bulk preparation process. Addition of a manufacturing site of the finished product.
•	22 April 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	26 July 2019	Introduction of a new pharmacovigilance system.
•	27 February 2019	Change of MAH from Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom to Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co. Galway, Ireland.
•	29 November 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.