



Post Authorisation Assessments

Adrenacaine Solution for Injection for Cattle Vm 02000/4243

•	23 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	12 September 2023	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. (GB)
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, BT35 6QQ, Co. Down, Northern Ireland.
•	11 October 2022	Substantial updates to an ASMF.
•	24 June 2022	Deletion of a manufacturer of an active substance.
•	19 August 2021	Change in the specification limits of the finished product.
•	18 September 2019	Update of the test procedure to comply with the updated general Ph. Eur monograph. Changes to a test procedure for the finished product.
•	27 August 2019	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	26 July 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	24 May 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	20 February 2019	Change of RMS from the UK to IE.
•	06 March 2015	Submission of an updated Ph. Eur. Certificate of Suitability.
•	23 January 2015	Renewal procedure – UK as RMS.
•	28 November 2014	Update to the DDPS.
•	21 March 2012	Change in distributor address.
•	30 June 2009	Repeat Use Procedure.
•	15 August 2007	Updates to bring the SPC and product literature in line with new legislation.
•	20 February 2007	To change legal category from PML to POM-VPS.
•	10 November 2005	Addition of a site of assembly.

•	25 July 2005	Change of name of the manufacturer of active substance.
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