



## Post Authorisation Assessments

### Adrenacaine Solution for Injection for Cattle Vm 02000/4243

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| • | 19 March 2024     | Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. (NI)   |
| • | 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.<br>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.<br>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   |

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|   |                  | 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. |