Veterinary Medicines Directorate

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Post Authorisation Assessments

Adrenacaine Solution for Injection for Cattle

Vm 02000/4243

15 April 2025	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (NI)
08 April 2025	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (GB)
03 April 2025	Alignment of the product information with version 9.0* of the QRD templates.
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. 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.