

Post Authorisation Assessments

Alamycin LA 200 mg/ml Solution for Injection for Cattle, Sheep and Pigs Vm 02000/4117

25 June 2025	Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range.
20 March 2025	SPC additional wording.
21 January 2025	Submission of an updated Ph. Eur. certificate of suitability for an active substance.
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.
08 July 2022	Change(s) in the SPC, labelling or package leaflet to section 4.5, 4.6 and 4.8.
23 January 2020	Changes to the withdrawal period of the veterinary medicinal product for all species.
23 January 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
23 January 2020	Deletion of a pack size of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Replacement to a test procedure for the finished product. Changes to a test procedure for the finished product. Change in the specification parameters and/or limits of the finished product. Change in the specification parameters and/or limits of the finished product. Changes in the composition (excipients) of the finished product.
23 January 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance.
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.
08 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
24 February 2016	Change in test procedure for the finished product.
13 January 2015	Submission of a new or updated Ph. Eur. certificate of suitability.
10 November 2014	Changes to an existing pharmacovigilance system as described in the DDPS

21 February 2013	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance.
19 December 2011	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance.
02 November 2011	Change in distributor details.
09 February 2011	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance.
27 February 2008	Changes to SPC/Product literature to keep in line with new legislation.
21 February 2008	Renewal.
07 February 2007	Change in legal category from POM to POM-V.
19 October 2005	Addition of site of assembly.
10 September 2004	Change in package composition.
12 March 2004	Renewal.
27 June 2003	Corrections/minor text changes to the SPC.
09 July 2002	Change in withdrawal period for cattle to 31 days.
12 April 2002	Change in manufacturer of active substance.
08 October 2001	Addition of a packaging presentation.
21 June 2001	Change in manufacturer of active substance.
16 July 1999	Change in withdrawal period to "8 days for ewes milk".
17 March 1999	Renewal.
09 September 1998	Change of manufacturing site of dosage form.
24 February 1998	Change in manufacturer of active substance.
23 July 1997	Change in manufacturer of the active substance. Change in therapeutic indications.
01 March 1996	Change in dosage particulars.