Veterinary Medicines Directorate

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Post Authorisation Assessments

Alamycin LA 300 Solution for Injection 300 mg/ml

Vm 02000/4113

•	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.
•	19 October 2022	Minor changes to an approved for the finished product.
•	11 July 2022	Change(s) in the SPC, labelling or package leaflet to section 4.5, 4.6 and 4.8.
•	26 March 2020	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product.
•	23 January 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance.
•	07 October 2019	Addition to a test procedure for the finished product.
•	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.
•	30 January 2018	Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	27 September 2017	Increase in batch size (including batch size range) of the finished product.
•	21 December 2016	Changes to the withdrawal period of the veterinary medicinal product.

•	13 January 2016	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 an updated Ph. Eur. Certificate of Suitability from an already approved manufacturer.
•	11 April 2012	Change in distributor details.
•	19 December 2011	Submission of a new/updated Ph. Eur. Certificate of Suitability for the active substance.
•	09 February 2011	Submission of a new/updated Ph. Eur. Certificate of Suitability for the active substance.
•	09 February 2009	Changes to the SPC and labels in line with new legislation.
•	08 July 2008	Renewal.
•	12 March 2008	Corrections/simple text/layout changes to the SPC/product literature.
•	18 December 2007	Change in packaging material not in contact with the finished product.
•	31 October 2007	Addition of 250ml and 500ml vial presentations.
•	07 February 2007	Change in legal category from POM to POM-V.
•	10 November 2005	Addition of a site of assembly.
•	21 July 2004	Renewal.
•	16 May 2003	Corrections/minor text changes to SPC and labels.
•	21 October 2002	Increase in milk withdrawal period for cattle from 7 days to 10 days.
•	12 April 2002	Change in manufacturer of active substance.
•	21 June 2001	Change in manufacturer of active substance.
•	02 February 1999	Extension to add sheep to list of target species.
•	18 December 1998	Renewal.
•	09 September 1998	Change of manufacturing site of dosage form.
•	08 May 1997	Change in manufacturer of active substance.
•	13 March 1997	Change in manufacturer of active substance.
•	05 July 1995	Change in withdrawal period (cattle and pigs).