Veterinary Medicines Directorate

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Post Authorisation Assessments

Bovaclox DC Intramammary Suspension

Vm 02000/4046

•	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.
•	27 July 2022	Minor changes to an approved test procedure for an active substance.
•	27 May 2021	Deletion of a non-significant specification parameter of an excipient.
•	02 October 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 May 2020	Change in immediate packaging of the active substance. Change in the name of a supplier of active substance and intermediate used in the manufacture of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Change in supplier of active substance. Deletion of a non-significant parameter of an active substance. Minor change to the restricted part of an Active Substance Master File.
•	26 November 2018	Change to a test procedure for the finished product.
•	26 November 2018	Increase in batch size of the finished product. Minor change in the manufacturing process.
•	10 July 2018	Tightening of specification limits of the immediate packaging of the finished product. Tightening of specification limits of the immediate packaging of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of

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•	31 May 2018	Deletion of a non-significant specification parameter of the finished product
•	11 July 2017	Deletion of manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance.
•	15 July 2013	Submission of 2 updated Ph. Eur. Certificates of Suitability
•	08 August 2012	Change of distributor address
•	09 January 2009	Changes to the SPC and Product Literature to bring in line with new legislation
•	20 February 2007	Change of legal category from POM to POM-V
•	28 February 2006	Renewal
•	29 November 2005	Addition of a manufacturer of an active substance
•	05 November 2004	Additional presentation
•	26 May 2004	Renewal
•	27 February 2004	Addition of a manufacturer of an active substance
•	05 June 2003	Increase of withdrawal period for milk from 49 days plus 96 hours to 49 days plus 216 hours
•	28 September 2001	Addition of a manufacturer of the active substance
•	23 July 2001	Harmonisation of the SPC
•	27 September 2000	Product harmonisation
•	02 September 1998	Renewal
•	25 April 1996	Additional presentation