Veterinary Medicines Directorate

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Post Authorisation Assessments

Bovaclox DC Xtra Intramammary Suspension

Vm 02000/4111

•	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 May 2021	Deletion of a non-significant specification parameter of an excipient.
•	06 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.
•	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.
•	06 December 2018	Change in the specification parameters and limits for an excipient from USNF to manufacturer's specification.
•	26 November 2018	Minor change in the manufacturing process of an oral solution. Increase in batch size (800 kg) of the finished product.
•	26 November 2018	Changes to a test procedure for the finished product.
•	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 the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product.
•	26 June 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.
•	01 May 2014	Addition of a manufacturer of an active substance.
•	15 July 2013	Submission of an updated Ph. Eur. Certificate of suitability
•	03 April 2012	Change of distributor address
•	22 December 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	24 October 2008	Renewal
•	20 February 2007	Change of legal category from POM to POM-V
•	16 November 2004	Renewal
•	28 November 2003	Renewal
•	06 June 2003	Increase in withdrawal period from 49 days plus 96 Hours to 49 days plus 120 hours
•	25 February 2003	Change in qualitative composition of the packaging
•	23 March 2001	Harmonisation of the SPC
•	03 November 2000	Addition of manufacturer of an active substance