Veterinary Medicines Directorate

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Post Authorisation Assessments

Betamox 150 mg/ml Suspension for Injection

Vm 02000/4071

•	26 May 2023	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	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.
•	27 January 2021	Reduction of the shelf life of the finished product as packaged for sale from 2 years to 12 months. Reduction of the shelf life of the finished product as packaged for sale from 2 years to 12 months.
•	18 September 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	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.
•	22 February 2019	Introduction of a new site of manufacture.
•	02 August 2018	Change in batch size of the finished product. Change in batch size of the finished product.
•	10 July 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph. Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	24 March 2017	Deletion of a manufacturing site of the active substance. Deletion of a manufacturing site of the active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance. Deletion of Ph. Eur. certificates of suitability for an active substance.
•	13 July 2016	Changes to a test procedure for the finished product.
•	10 November 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	20 October 2014	Change to the name of an excipient, from ‘Coconut Oil, Fractioned' to 'Propylene Glycol Dicaprylocaprate'.

•	18 April 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer.
•	13 December 2012	To introduce plastic vials as immediate packaging of the finished product, with a proposed shelf life of 24 months.
•	11 September 2012	Submission of a new Ph. Eur. Certificate of Suitability for an active substance.
•	18 July 2012	Change of distributor.
•	31 July 2008	Changes to the SPC and Product Literature to bring in line with new legislation.
•	31 July 2007	Addition of manufacturer of the active substance.
•	20 February 2007	Change of legal category from POM to POM-V.
•	08 March 2006	Change of manufacturer of the active substance. Submission of a new Ph. Eur. Certificate of Suitability.
•	11 January 2006	Addition of manufacturing site for part of the manufacturing process.
•	05 January 2006	Renewal.
•	10 November 2005	Change of method of manufacture of the active substance.
•	11 August 2005	Addition of a site of assembly for the finished product.
•	21 September 2001	Addition of a manufacturer of the active substance.
•	31 May 2001	Renewal.
•	03 March 1998	Change of safety warnings.
•	24 February 1998	Change of withdrawal period.
•	19 July 1996	Renewal.