Veterinary Medicines Directorate

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Post Authorisation Assessments

Betamox LA 150 mg/ml Suspension for Injection

Vm 02000/4070

•	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.
•	11 May 2022	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	01 March 2022	Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a PSUR.
•	07 June 2021	Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	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.
•	24 November 2020	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	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.
•	15 January 2019	Increase of withdrawal periods.
•	02 August 2018	Change in batch size of the finished product. Change in batch size of the finished product.
•	07 March 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	09 January 2018	Replacement of a supplier of packaging components or devices.
•	29 December 2016	Deletion of a manufacturing site of the active ingredient. Deletion of a manufacturing site of the active ingredient. Submission of an updated certificate of suitability. Submission of an updated certificate of suitability.

		Deletion of a certificate of suitability.
•	05 September 2016	Changes to a test procedure for the finished product.
•	16 February 2016	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	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 certificate of suitability.
•	21 November 2012	Change in pack size.
•	11 September 2012	Submission of a new Ph. Eur. Certificate of Suitability for an active substance.
•	18 December 2008	Changes to the SPC and Product Literature to bring in line with new legislation.
•	01 August 2007	Addition of a manufacturer of the active substance.
•	20 February 2007	Change of legal category from POM to POM-V.
•	11 January 2006	Addition of a manufacturing site involved in the manufacturing process of the active substance.
•	05 January 2006	Renewal.
•	10 November 2005	Addition of a manufacturing site involved in the manufacturing process of the active substance.
•	24 August 2005	Addition of a site of assembly.
•	18 September 2002	Renewal.
•	21 September 2001	Addition of a manufacturer of the active substance.
•	03 March 1998	Addition of a user safety warning.
•	26 September 1996	Renewal.