Veterinary Medicines Directorate

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Post Authorisation Assessments

Betamox LA 150 mg/ml Suspension for Injection

Vm 02000/4070

October 2026	Change of specifications outside the previously accepted range. Addition of a specification parameter with corresponding test method.
28 July 2025	Extension of the shelf life of the finished product as packaged for sale.
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.