Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Nelio 2.5 mg Tablet for Cats

Vm 15052/4107

•	15 August 2023	Change in qualitative or quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product.
•	14 March 2023	Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient.
•	12 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	07 January 2020	Minor changes to an approved test procedure of the finished product.
•	23 May 2019	Replacement of a site where batch control/testing takes place
•	22 November 2018	Replacement of a manufacturer responsible for batch release of the finished product. Deletion of a packaging site.
•	19 September 2017	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.
•	14 June 2017	Deletion of a non-significant specification parameter of an excipient.
•	18 May 2017	Deletion of a manufacturing site of an active substance.
•	10 November 2016	Change in name / address of a manufacturer of the finished product. Change in name / address of a manufacturer of the finished product. Change in name / address of a manufacturer of the finished product.
•	28 July 2016	Repeat use (UK comment only)
•	29 June 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	16 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd.
•	07 January 2016	Deletion of a manufacturing site of the active substance. Submission of a new or updated Ph. Eur. certificate of suitability. Submission of a new or updated Ph. Eur. certificate of

		suitability.
•	06 August 2015	Changes to the labelling and package leaflet. Change of distributor.
•	23 December 2014	Renewal.
•	21 December 2012	Implementation of changes to SPC and product literature in accordance with an EMA referral.
•	20 November 2012	Extension of finished product shelf life.
•	20 November 2012	Change in storage conditions of the finished product.
•	08 November 2012	To introduce a new retest period for the active substance.
•	13 July 2012	To submit a new Ph. Eur certificate of suitability from a new manufacturer of the active substance.
•	17 May 2010	To replace the site for primary packaging and add a supplementary site for secondary packaging.
•	25 March 2010	To replace the finished product manufacturer.