Veterinary Medicines Directorate

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Post Authorisation Assessments

Nelio 5 mg Tablet for Dogs

Vm 15052/4110

•	22 February 2024	Addition of an immediate packaging for the finished product. (NI)
•	22 February 2024	Change in shelf life of the desiccant blister packs.
•	15 August 2023	Change in qualitative or quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product. (GB)
•	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.
•	06 October 2021	Change in the SPC, labelling or package leaflet due to new data.
•	25 March 2020	Reduction of the shelf life of the finished product as packaged for sale from 2 years to 1 year.
•	07 January 2020	Minor changes to an approved test procedure of the finished product.
•	10 October 2019	Change in storage conditions 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.
•	10 September 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	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.
•	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.
•	29 August 2014	To extend the shelf life of the finished product, from 21 months to 24 months.
•	27 March 2014	Renewal procedure – France as RMS.
•	24 September 2013	Additional batch size of the finished product.
•	21 December 2012	Implementation of changes to SPC and product literature in accordance with an EMA referral.
•	08 November 2012	Variation to introduce a re-test period for the active substance from one of the active substance manufacturers.
•	13 July 2012	To submit a new Ph. Eur certificate of suitability from a new manufacturer of the active substance.
•	17 May 2010	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	25 March 2010	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.