Veterinary Medicines Directorate

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Post Authorisation Assessments

Nelio 20 mg Tablet for Dogs

Vm 15052/4108

07 May 2025	Deletion of a non-significant specification parameter for an excipient. (GB).
18 January 2025	Deletion of a Ph. Eur. CEP for an active substance. (NI).
14 December 2024	Deletion of a Ph. Eur. CEP for an active substance. (GB)
27 October 2024	Deletion of a non-significant specification parameter in the specification parameters of an excipient. Deletion of a non-significant specification parameter in the specification parameters of an excipient. Deletion of a non-significant specification parameter in the specification parameters of an excipient. Deletion of a non-significant specification parameter in the specification parameters of an excipient. Deletion of a non-significant specification parameter in the specification parameters of an excipient. (NI)
16 August 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
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.
06 October 2021	Change in the SPC, labelling or package leaflet due to new data.
10 September 2021	Reduction of the shelf life of the finished product as packaged for sale from 3 to 2 years. Change in the specification limits of the finished product.
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 36 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.