

Post Authorisation Assessments

Nelio 5 mg Tablet for Cats Vm 14966/5019

17 February 2026	Approval of mock-ups.
01 October 2025	Change in legal entity of MA holder from: Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom to Ceva Santé Animale, 8 rue de Logrono, 33500 Libourne, France.
02 September 2025	Deletion of a non-significant specification parameter of an excipient. (NI) Deletion of a non-significant specification parameter of an excipient. (NI) Deletion of a non-significant specification parameter of an excipient. (NI) Deletion of a non-significant specification parameter of an excipient. (NI) Deletion of a non-significant specification parameter of an excipient. (NI)
22 July 2025	Deletion of a Ph.Eur. CEP for an active substance. (GB).
11 June 2025	Deletion of a non-significant specification parameter for an excipient. (NI).
10 June 2025	Alignment of the product information with version 9.0* of the QRD templates.
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).
18 January 2025	Submission of a new Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (GB).
16 August 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
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.
26 September 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.
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	Change in shelf life of the finished product from 21 months to 24 months.
20 February 2014	Renewal.
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	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.
25 March 2010	Change in batch size of the finished product.