



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Nexgard Spectra 9 mg / 2 mg Chewable Tablets for Dogs 1.35–3.5 kg Vm 04491/5035

30 April 2025	Change in batch size of active substance intermediate more than 10-fold increase compared to the originally approved batch size. Change in batch size of active substance more than 10-fold increase compared to the originally approved batch size.
20 July 2024	Change in the name and address details of a manufacturer or supplier of the active substance.
28 April 2024	Addition of a manufacturer of a starting material used in the manufacturing process of the active substance where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
02 April 2024	One-off alignment of the product information with version 9.0* of the QRD template. Lowering of the minimum bodyweight from 2.0 -3.5kg to 1.35 - 3.5kg.
21 December 2023	Change to an approved stability protocol of the finished product
10 October 2023	Change in the shelf-life of the finished product: - Extension of the shelf life of the finished product - As packaged for sale.
22 August 2023	Addition of a new supplier of a starting material used in the manufacturing process of the active substance. Addition of a new supplier of a starting material used in the manufacturing process of the active substance. Addition of a new supplier of a starting material used in the manufacturing process of the active substance.
09 June 2023	Change in batch size for intermediate used in the manufacturing process of the active substance.
24 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
17 April 2023	Change in the Summary of Product Characteristics, Labelling or Package Leaflet due to new clinical data. Addition of a new therapeutic indication or modification of an approved one. Addition of a new therapeutic indication or modification of an approved one.
23 August 2022	Change in address of manufacturer of the finished product.
19 May 2022	Updates to the ASMF.
28 April 2022	Increase in batch size (from 636kg to 656kg) of the active substance used in the manufacturing process of the active substance.
April 2022	Change in immediate packaging of the active substance.
23 February 2022	Changes to the labelling and/or package leaflet.
15 February 2022	Deletion of a supplier of packaging components or devices.
04 August 2021	Extension of a re-test period of the active substance.
25 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.

