



Post Authorisation Assessments

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

Nexgard Spectra 38 mg / 8 mg Chewable Tablets for Dogs >7.5–15 kg Vm 04491/5033

• 15 October 2024	Replacement or addition of a primary packaging site of a non-sterile finished product.
• 23 August 2024	Addition of a manufacturing site for the finished product.
• 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.
• 29 April 2022	Change in immediate packaging of the active substance.
• 29 April 2022	Increase in batch size (from 636 kg to 636 kg or 656 kg) of the active substance used in the manufacturing process 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.