



## Post Authorisation Assessments

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

### Nexgard Spectra 9 mg / 2 mg Chewable Tablets for Dogs 1.35–3.5 kg Vm 61700/5032

02 April 2026	Deletion of a non-significant specification parameter of an active substance.
11 February 2026	<p>One-off alignment of the product information with version 3 of the QRD template.</p> <p>For reduction of the risk of infection with <i>Babesia canis</i> via transmission by <i>Dermacentor reticulatus</i> for 28 days. The effect is indirect due to the activity of the veterinary medicinal product against the vector.</p> <p>For reduction of the risk of infection with <i>Dipylidium caninum</i> via transmission by <i>Ctenocephalides felis</i> for 30 days. The effect is indirect due to the activity of the veterinary medicinal product against the vector.</p> <p>Minor amendment to Section 3.9: Treatment of demodicosis: Administration of the veterinary medicinal product leads to a marked improvement of clinical signs. Treatment should be continued until two negative skin scrapings are obtained one month apart. Severe cases may require prolonged monthly treatments. As demodicosis is a multi-factorial disease, where possible, it is advisable to also treat any underlying disease appropriately.</p>
09 December 2025	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.
09 September 2025	Addition of a primary packaging site of a non-sterile finished product.
23 July 2025	<p>Change in the manufacturing process of the finished product:- change in the holding time of a bulk product.</p> <p>Addition of a manufacturing site for part or all of the manufacturing process of the finished product.</p>
11 June 2025	Deletion of a non-significant specification parameter for an active substance.
10 June 2025	<p>Change in the specification parameters of an active substance.</p> <p>Change in the specification parameters of an active substance.</p> <p>Submission of a new CEP for the manufacture of an active substance.</p> <p>Submission of a new CEP for the manufacture of an active substance.</p>
30 April 2025	<p>Change in batch size of active substance intermediate more than 10-fold increase compared to the originally approved batch size.</p> <p>Change in batch size of active substance more than 10-fold increase compared to the originally approved batch size.</p>
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.