



Post Authorisation Assessments

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

NexGard 11 mg Chewable Tablets for Dogs 2-4 kg Vm 04491/5027

12 December 2024	One-off alignment of the product information with version 9.0* of the QRD templates
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.
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.
06 June 2023	Change in batch size for intermediate used in the manufacturing process of the active substance.
24 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
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.
14 October 2022	Addition of a site of batch control.
14 October 2022	Addition of a site responsible for primary packaging.
13 October 2022	Addition of a manufacturing site for the manufacturing process of the finished product.
23 August 2022	Change in address of manufacturer of the finished product.
08 June 2022	Changes to labelling.
29 April 2022	Change in immediate packaging of the active substance.
28 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.
15 February 2022	Deletion of a supplier of packaging components or devices.
02 September 2021	Change in shape or dimensions of the container or closure (immediate packaging). Minor change in the manufacturing process of the finished product. Deletion of a non-significant specification parameter of an excipient.
25 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.