Veterinary Medicines Directorate
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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

NexGard 136 mg Chewable Tablets for Dogs >25-50 kg

Vm 61700/5031

28 July 2026	Addition of a new manufacturer of a starting material used during the manufacturing process of the active substance.
26 May 2026	Addition of a new manufacturer of a starting material used during the manufacturing process of the active substance. Addition of a new manufacturer of a starting material used during the manufacturing process of the active substance. Change to in-process tests or limits applied during the manufacture of the active substance. Changes in the manufacturing process of the active substance.
02 April 2026	Deletion of a non-significant specification parameter of an active substance.
12 December 2025	For reduction of the risk of infection with Dipylidium caninum via transmission by Ctenocephalides felis for 30 days. The effect is indirect due to the activity of the veterinary medicinal product against the vector. For reduction of the risk of infection with Babesia canis via transmission by Dermacentor reticulatus for 28 days. The effect is indirect due to the activity of the veterinary medicinal product against the vector. 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.
08 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.
13 June 2025	Deletion of a non-significant specification parameter in the specification parameters or limits of an active substance.
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.
04 March 2025	Change in the batch size of the finished product.
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.