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 28 mg Chewable Tablets for Dogs >4-10 kg

Vm 04491/5029

•	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.