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 Spectra 38 mg / 8 mg Chewable Tablets for Dogs >7.5–15 kg

Vm 04491/5033

•	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.