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Post Authorisation Assessments

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

NexGard Combo Spot-On Solution for Cats <2.5 kg

Vm 04491/5000

• 04 May 2024	Section 4.5i) of the SPC and section 12 of the package leaflet
	were amended in relation to the accumulation of the active
	substances and in relation to repeated treatments beyond 6
	consecutive months.
• 14 February 2024	Addition of a site of batch control for the finished product.
• 01 June 2023	Change in the shelf-life or storage conditions of the finished product: - Change in storage conditions of the finished product or the diluted/reconstituted product.
• 21 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
• 07 November 2022	Addition of a new in-process test applied during manufacture of the active substance.
• 22 July 2022	Deletion of a test procedure for the active substance.
• 13 July 2022	Minor changes to an approved test procedure for the active substance.
• 28 April 2022	Increase in batch size of the active substance used in the
	manufacturing process of the active substance.
• 15 February 2022	Change in the name of a manufacturer used in the
	manufacture of the active substance.
• 06 January 2022	Change in the name/address of a manufacturer used in the
	manufacture of the active substance.
• 22 December 2021	Change in the SPC, labelling or package leaflet due to new
	data.
	Addition of a new therapeutic indication.
	Addition of a new therapeutic indication.
• 30 September 2021	Change to an approved stability protocol.
• 06 July 2021	Extension of a re-test period of the active substance.