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Post Authorisation Assessments

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

Procox 0.9 mg/ml + 18 mg/ml Oral Suspension for Dogs Vm 06462/5005

•	07 November 2023	Addition of a site responsible for quality testing of the finished product.
		Addition of a new IPC applied during the manufacturing
		process. Minor change to an approved test procedure for an active
		substance.
		Minor change to an approved test procedure for an active substance.
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		substance.
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		substance.
		Minor changes to an in-process limit range for the finished product.
		Addition of a site responsible for batch release of the finished
		product.
		Addition of a site responsible for primary packaging of the
		finished product.
		Addition of a site responsible for secondary packaging of the
		finished product.
•	11 August 2023	Change in test procedure for the finished product.
		Change in the batch size (including batch size ranges) of the finished product.
		Change in the manufacturing process of the finished product,
		including an intermediate used in the manufacture of the
		finished product.
		Change in the specification parameters and/or limits of the
		finished product.
		Change to in-process tests or limits applied during the
		manufacture of the finished product: - Other changes.
		Replacement or addition of a manufacturing site for part or all
•	11 May 2023	of the manufacturing process of the finished product. Change in immediate packaging of the finished product.
		Change in the specification parameters and/or limits of the
		immediate packaging of the finished product.
•	08 October 2021	Minor change of an analytical procedure for an in-process
		control during the manufacture of the finished product.
•	20 July 2021	Introduction of a new pharmacovigilance system.