Veterinary Medicines Directorate

Veterinary Medicines Directorate Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

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

Vectra 3D Spot-on Solution for Dogs 10-25 kg

Vm 15052/5022

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•	14 May 2024	Change in the name of the ASMF holder for an active substance.
		Change in the name of the ASMF contact for an active substance.
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•	04 May 2024	Change in the address of an active substance master file holder.
		Change in the name and contact details of an active substance
		master file holder.
		Deletion of a non-significant specification parameter of an
		active substance.
•	13 April 2024	Change in the specification parameters and/or limits of an
		active substance.
•	11 October 2023	Changes in the Summary of Product Characteristics (SPC),
•		labelling or package leaflet intended to implement the outcome
		of a Union interest referral procedure according to Article 83 of
		Regulation (EU) 2019/6.
	20 October 2022	Change in the address of the MAH from Unit 3 Anglo Office
•		
		Park, White Lion Road Amersham, Buckinghamshire HP7 9FB
		to Explorer House, Mercury Park, Wycombe Lane, Wooburn
		Green, High Wycombe, Buckinghamshire, HP10 0HH, United
	00.14	Kingdom.
•	26 May 2022	Update to User Safety warnings
	10 February 2022	Addition of a manufacturer responsible for batch release of the finished product.
	02 December 2021	Change in the manufacturer of a starting material used in the
		manufacturing process of the active.
•	12 July 2021	Minor change in the manufacturing process of the active
		substance.
		Minor change in the manufacturing process of the active
		substance.
•	17 June 2021	Changes to the quality control testing arrangements for the
		active substance - addition of a site where batch control takes
		place.
		Addition of a site where batch control takes place.
•	26 February 2021	Change in shape or dimensions of the container or closure
		(immediate packaging)
		Change in shape or dimensions of the container or closure
		· ·
		(immediate packaging)