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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.

Apoquel 16mg Film-coated Tablet for Dogs

Vm 42058/5005

• 2	20 February 2024	List of EU Local Representatives deleted from GB QRD
		documents.
• 3	31 August 2023	Added to Safety Sections the adverse event 'Convulsion' with
		the frequency of Very rare: <1 animal / 10,000 animals treated,
		including isolated reports.
• 1	15 June 2023	Minor changes to an approved test procedure for active
		substance.
• 0	01 June 2023	One-off alignment of the product information with version 9.0*
		of the QRD template.
• 2	23 December 2022	Minor changes to an approved test procedure, for a starting
		material, reagent or intermediate used in the manufacturing
		process of the active substance.
• 2	23 December 2022	Minor changes to an approved test procedure for active
		substance.
• 0	1 November 2022	Change in name and address details of a manufacturer of the
		active substance.
• 1	11 October 2022	Deletion of suppliers of packaging components from the
		product dossier.
• 2	22 February 2022	Change in the manufacturing process of the finished product.
• 0	05 August 2021	Changes to the labelling and/or package leaflet.
• 2	28 July 2021	Change in the manufacturer of an intermediate used in the
	-	manufacturing process of the active and change in a
		manufacturer of the active
• 0	06 May 2021	Change in immediate packaging of the finished product
• 2	22 February 2022 05 August 2021 28 July 2021	product dossier. Change in the manufacturing process of the finished product. Changes to the labelling and/or package leaflet. Change in the manufacturer of an intermediate used in the manufacturing process of the active and change in a manufacturer of the active