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.

Apoquel 5.4 mg Chewable Tablets for Dogs

Vm 42058/5001

•	12 March 2024	Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range.
•	12 March 2024	List of EU Local Representatives deleted from GB QRD documents.
•	15 September 2023	Change in the shelf-life or storage conditions of the finished product: - Extension of the shelf life of the finished product - As packaged for sale.
•	25 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.
•	15 June 2023	Minor changes to an approved test procedure for active substance.
•	14 June 2023	Change in test procedure for an excipient: - Other changes to a test procedure (including replacement or addition).
•	01 June 2023	One-off alignment of the product information with version 9.0* of the QRD template.
•	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.
•	23 December 2022	Minor changes to an approved test procedure for active substance.
•	01 November 2022	Change in name and address details of a manufacturer of the active substance.
•	28 June 2022	Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacture.
•	20 May 2022	Change in the number of units (blister) in a pack within the range of the currently approved pack sizes of the finished product.
•	18 May 2022	Change in test procedure for an excipient.