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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 16 mg Chewable Tablets for Dogs

Vm 42058/5002

1 July 2026	Minor changes to an approved test procedure for the finished product.
13 May 2026	Clarifications to dosing table regarding animal weights and numbers of tablets.
16 February 2026	Change in the test procedure for an excipient.
22 December 2025	Change to batch control arrangements and quality testing for a finished product.
22 December 2025	Removal of references to the local representative.
04 September 2025	Minor change in the manufacturing process of the finished product. Change in the holding time of the bulk product.
04 July 2025	Change to comply with Ph. Eur.
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.