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.

Apoquel 3.6mg Film-coated Tablet for Dogs

Vm 42058/5006

16 April 2025	Removal of mention of local representatives from SPC and QRD. As well as changes to contact details to reflect no local representatives.
20 February 2024	List of EU Local Representatives deleted from GB QRD documents.
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.
15 June 2023	Minor changes to an approved test procedure for active substance.
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.
11 October 2022	Deletion of suppliers of packaging components from the product dossier.
22 February 2022	Change in the manufacturing process of the finished product.
05 August 2021	Changes to the labelling and/or package leaflet.
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
06 May 2021	Change in immediate packaging of the finished product