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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.

Cardalis 5 mg/40 mg Chewable Tablets for Dogs

Vm 15052/5005

•	06 September 2023	Submission of an updated Ph. Eur. CEP for an already approved manufacturer of an active substance.
•	28 April 2023	Change(s) in the SPC, labelling or package leaflet, to section 4.6 and 6 Adverse reactions.
•	19 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 Kingdom.
•	08 July 2022	Additional quality control site for the finished product. Deletion of a non-significant specification parameter of an excipient. Minor changes to an approved test procedure for an excipient.