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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 10 mg/80 mg Chewable Tablets for Dogs

Vm 15052/5003

| • | 06 September 2023 | Submission of an updated Ph. Eur. CEP for an already approved manufacturer of an active substance. |
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| • | 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. |