



## Post Authorisation Assessments

### Prilactone Next 10 mg Chewable Tablets for Dogs Vm 15052/5063

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| • | 14 May 2024       | Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product.<br>Replacement or addition of a primary packaging site of a non-sterile finished product.<br>Replacement or addition of a secondary packaging site of a finished product. |
| • | 12 May 2023       | Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer. (NI)  |
| • | 13 January 2023   | Minor changes to an approved test procedure for the active substance.  |
| • | 11 January 2023   | Updated certificate of suitability from an already approved manufacturer.  |
| • | 30 December 2022  | Change in the specification limits of the immediate packaging of the finished product.   |
| • | 12 October 2022   | Minor changes to an approved test procedure for the active substance.  |
| • | 12 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.   |
| • | 29 June 2020      | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.  |
| • | 23 May 2019       | Replacement of a site where batch control/testing takes place  |
| • | 03 May 2018       | Deletion of a manufacturing site for a packaging site and manufacturer responsible for batch release.  |
| • | 05 January 2018   | Deletion of a non-significant specification parameter of an excipient.   |
| • | 19 September 2017 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.<br>Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.  |
| • | 29 June 2017      | Renewal – UK as CMS.   |
| • | 10 March 2017     | Change in the invented name of the veterinary medicinal product from Tempora 10 mg Chewable Tablets for Dogs to Prilactone Next 10 mg Chewable Tablets for Dogs.<br>Changes to the outer carton labelling, which are not connected with the SPC.   |

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| • | 19 December 2016 | Submission of an updated certificate of suitability.  |
| • | 10 November 2016 | Change in name / address of a manufacturer of the finished product.<br>Change in name / address of a manufacturer of the finished product.<br>Change in name / address of a manufacturer of the finished product. |
| • | 06 October 2016  | Approval of change to design/layout of mock-ups.  |
| • | 29 June 2016     | Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.  |
| • | 14 June 2016     | Change of MAH, from Sogeval to Ceva Animal Health Ltd and Change of Distributor to Ceva Animal Health Ltd.  |
| • | 23 January 2013  | Approval of mock-ups.   |