Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Prilactone Next 50 mg Chewable Tablets for Dogs

Vm 15052/4117

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| • | 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. |
| • | 06 October 2021 | Change in the SPC, labelling or package leaflet due to new data. |
| • | 29 June 2020 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 27 May 2020 | Change in shape or dimensions of the container or closure (immediate packaging). |
| • | 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. |
| • | 28 June 2017 | Renewal – UK as CMS |
| • | 10 March 2017 | Change in the invented name of the veterinary medicinal product from Tempora 50 mg Chewable Tablets for Dogs to Prilactone Next 50 mg Chewable Tablets for Dogs.<br>Changes to the outer carton labelling, which are not connected with the SPC. |
| • | 19 December 2016 | Submission of an updated certificate of suitability. |
| • | 10 November 2016 | Change in name / address of a manufacturer of the finished product. |

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| | | 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. |
| • | 25 April 2014 | Change to the local representative in Poland and resulting mock-up changes that do not affect the UK. |
| • | 23 January 2013 | Approval of mock-ups. |