Veterinary Medicines Directorate

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Post Authorisation Assessments

Prilactone Next 50 mg Chewable Tablets for Dogs

Vm 15052/5064

•	14 May 2024	Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product. Replacement or addition of a primary packaging site of a non-sterile finished product. 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.
•	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. 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. 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. Change in name / address of a manufacturer of the finished product. 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.