Veterinary Medicines Directorate

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Post Authorisation Assessments

Kesium 200 mg / 50 mg Chewable Tablets for Dogs

Vm 15052/4131

•	12 June 2023	Change in pack size of the finished product: - Change in the number of units in a pack outside the range of the currently approved pack sizes.
•	22 March 2023	Deletion of a non-significant in-process tests during the manufacture of the finished product.
•	14 March 2023	Minor change in the manufacturing process of the finished product.
•	18 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.
•	07 October 2021	Changes to the labelling and package leaflet.
•	06 October 2021	Change in the SPC, labelling or package leaflet due to new data.
•	10 September 2021	Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product.
•	09 September 2021	Addition of a site where batch control/testing takes place. Addition of a primary packaging site of the finished product. Increase in batch size (from 133.000 tablets (100kg), 200.000 tablets (150 kg), 400.000 tablets (300 kg) to Pencef site: 133.000 tablets (100kg) / 200.000 tablets (150 kg) / 400.000 tablets (300 kg), Ceva site: 120/250/285/500 kg of final blend bulk) of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form. Tightening of in-process limit applied during the manufacture of the finished product. Addition of a manufacturing site of the finished product.
•	15 July 2021	Deletion of a non-significant specification parameter of the immediate packaging of the finished product.

•	06 July 2021	Deletion of a non-significant specification parameter of an excipient. Deletion of a non-significant specification parameter of an excipient. Minor change to an approved test procedure for an excipient. Minor change to an approved test procedure for an excipient.
•	17 June 2021	Change in the invented name of the veterinary medicinal product from Kesium 250 mg Chewable Tablets for Dogs to Kesium 200 mg / 50 mg Chewable Tablets for Dogs.
•	03 March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	03 April 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	24 July 2018	Change in the invented name of the veterinary medicinal product in DK only.
•	12 June 2018	Change in the address of the manufacturer of the finished product. Deletion of a manufacturing site responsible for batch release. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	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.
•	09 November 2016	Change in the name of a manufacturer of the finished product. Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release. Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release.
•	21 October 2016	Mock-ups approved. Change in distributor details from Alstoe Ltd to Ceva Animal Health Ltd.
•	19 August 2016	Change of Marketing Authorisation Holder from Sogeval to Ceva Animal Health Ltd.
•	09 August 2016	Submission of an updated certificate of suitability.
•	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.
•	08 June 2016	Renewal – UK as CMS
•	16 February 2016	Submission of an updated Ph. Eur. certificate of suitability.

		Deletion of a Ph. Eur. certificate of suitability
•	4 December 2015	Replacement of a secondary packaging site.
•	19 July 2013	Change of shape of the pharmaceutical form Change of shape/dimensions of the immediate packaging Change of manufacturing process of the finished product Change of break lines/scoring of the finished product
•	31 May 2013	Submission of Ph. Eur. Certificates of Suitability for an active substance from 2 already approved manufacturers. Replacement of a new Ph. Eur. Certificate of Suitability for an active substance from a new manufacturer.
•	18 July 2012	Shelf life of the product was increased from 30 to 36 months.