



## Post Authorisation Assessments

### **Kesium 500 mg / 125 mg Chewable Tablets for Dogs** Vm 15052/3035

•	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.
•	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	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 160.000 tablets (300kg), 100.000 tablets (187.5kg) to Pencef site: 160.000 tablets (300kg) /100.000 tablets (187.5kg) 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. Addition of a manufacturing site of the finished product.
•	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. Changes to a test procedure for 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

		<p>an excipient.</p> <p>Minor change to an approved test procedure for an excipient.</p> <p>Minor change to an approved test procedure for an excipient.</p>
•	17 June 2021	Change in the invented name of the veterinary medicinal product from Kesium 625 mg Chewable Tablets for Dogs to Kesium 500 mg / 125 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	<p>Change in the address of the manufacturer of the finished product.</p> <p>Deletion of a manufacturing site responsible for batch release.</p> <p>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.</p> <p>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.</p>
•	16 May 2018	Renewal – UK as CMS.
•	19 September 2017	<p>Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.</p> <p>Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.</p>
•	09 November 2016	<p>Change in the name of a manufacturer of the finished product.</p> <p>Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release.</p> <p>Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release.</p>
•	21 October 2016	<p>Mock-ups approved.</p> <p>Change in distributor details from Alstoe Ltd to Ceva Animal Health Ltd.</p>
•	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.
•	16 February 2016	<p>Submission of an updated Ph. Eur. certificate of suitability.</p> <p>Deletion of a Ph. Eur. certificate of suitability</p>
•	4 December 2015	Replacement of a secondary packaging site.

•	28 November 2014	To increase the shelf-life of the veterinary medicinal product as packaged for sale, from 24 months to 36 months.
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