Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

## **Post Authorisation Assessments**

## Kesium 40 mg / 10 mg Chewable Tablets for Cats and Dogs $\,$ Vm 15052/3031

•	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.
•	21 March 2023	Deletion of a non-significant in-process tests during the manufacture of the finished product.
•	21 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.
•	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 666.000 tablets (100kg), 1.250.000 tablets (187.5kg) to Pencef site: 666.000 tablets (100kg) / 1.250.000 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.  Tightening of in-process limit applied during the manufacture of the finished product.  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.  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

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•   10   EDITIALLY 20 10   Submission of all updated Fil. Lul. Certificate of	•	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.	•	4 December 2015	

•	31 May 2013	Submission of two updated Ph. Eur. Certificates of
		Suitability for an active substance from two already
		approved manufacturers.
		Replacement of a new Ph. Eur. Certificate of Suitability
		for an active from a new manufacturer.