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Post Authorisation Assessments

Veloxa XL Chewable Tablets for Dogs

Vm 32823/4011

	16 May 2024	Change in mothed of analysis of the costing
•	16 May 2024	Change in method of analysis of the active substance to comply with the Ph. Eur. monograph. Change in method of analysis of the active substance to comply with the Ph. Eur. monograph. Change to an active substance specification to comply with the Ph. Eur. monograph. Submission of an updated Ph. Eur. CEP for a manufacturer of the active substance. Submission of an updated Ph. Eur. CEP for a
		manufacturer of the active substance.
•	17 November 2023	Change in method of analysis of the active substance to comply with the Ph. Eur. monograph. Change in method of analysis of the active substance to comply with the Ph. Eur. monograph. Change to an active substance specification to comply with the Ph. Eur. monograph. Submission of an updated Ph. Eur. CEP for a manufacturer of the active substance. Submission of an updated Ph. Eur. CEP for a manufacturer of the active substance. (GB)
•	09 June 2020	Change in the address of the marketing authorisation holder from Lavet Pharmaceuticals Ltd., Ottó u. 14., 1161 Budapest, Hungary to Lavet Pharmaceuticals Ltd., Batthyány u. 6., 2143 Kistarcsa, Hungary.
•	11 November 2019	Deletion of manufacturing site for an active substance. 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.

•	26 July 2019	Change in distributor details from Merial Animal Health Ltd, PO Box 327, Sandringham House, Harlow Business Park, Harlow, Essex CM19 5TG to
		Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire RG12 8YS.
•	05 March 2019	Changes to the labelling, or the package leaflet, which are not connected with the SPC.
•	06 December 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
•	24 January 2018	To increase the shelf life of the finished product as packaged for sale, from 2 years to 3 years.
•	23 June 2017	Renewal – UK as CMS.
•	12 September 2016	Submission of an updated certificate of suitability. Submission of an updated certificate of suitability.
•	15 April 2014	Change of the invented medicinal product name in Italy only.
•	05 April 2013	Change to the invented name of the product from Xindex XL Chewable Tablets for Dogs to Veloxa XL Chewable Tablets for Dogs.