



Post Authorisation Assessments

Leventa 1 mg/ml Oral Solution for Dogs Vm 01708/4527

• April 2024	Change in the dimensions of the immediate packaging for the finished product. (NI)
• 25 January 2024	Alternative primary packaging container registered for the finished product. (GB)
• 25 August 2021	Addition of a site where batch control/testing takes place.
• 27 April 2021	Addition of a site where batch control/testing takes place.
• 27 April 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
• 14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
• 13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
• 16 January 2018	Change in the specification limits of the finished product.
• 01 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
• 27 April 2016	Submission of an updated Ph. Eur. certificate of suitability.
• 02 April 2014	Reduction in the shelf-life of the finished product, from 3 years to 2 years.
• 27 November 2014	Update of the pharmacovigilance system as described in the DDPS.
• 06 October 2014	Change in specification limit of the finished product.
• 22 October 2012	Changes to the DDPS following assessment of the same DDPS in relation to another medicinal product of the same MAH.
• 13 June 2012	Renewal procedure – Ireland as RMS.
• 18 March 2009	Change shelf life of finished product (as packaged for sale)
• 19 November 2008	Simple dosage instruction changes
• 22 May 2008	Change shelf life of finished product (after first opening)
• 22 May 2008	Formulation
• 04 July 2007	Deletion of any manufacturing site