



Post Authorisation Assessments

Canigen Lepto 2 Vm 01708/4493

•	12 May 2022	Submission of a new Ph. Eur. certificate of suitability. Submission of a new Ph. Eur. certificate of suitability.
•	22 July 2021	Changes in the SPC, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR. Change in the specification limits of the finished product.
•	21 March 2021	Deletion of a pack sizes of the finished product. Change in the composition (excipients) of the finished product.
•	05 November 2020	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	16 April 2019	Change in the batch size of the active substance used in the manufacturing process of the active substance. Change in the fill volume of the finished product. Changes in the manufacturing process of the active substance.
•	20 April 2016	Change in part of the (primary) packaging material not in contact with the finished product formulation. Approval of mock-ups.
•	23 December 2015	Change in the specification limits of the finished product
•	17 April 2013	Change in test procedure performed on the finished product Change to in process tests performed during the manufacturing process of the active substances
•	03 January 2013	Change in manufacturing process of the active substances
•	22 December 2010	Change to minimum age of administration
•	13 January 2010	Minor change to SPC and Product Literature
•	11 September 2008	Change of test performed on the finished product
•	11 June 2008	Minor changes to SPC and Product Literature Change of quantitative and qualitative composition of the packaging
•	16 May 2008	Renewal
•	11 October 2006	Corrections to the SPC and Product Literature
•	22 August 2006	Changes to the SPC and Product Literature to bring in line with new legislation
•	05 April 2006	Addition of a presentation Change in product composition
•	26 May 2005	Change of batch size of the active substance

•	24 October 2003	Addition of a manufacturer of an active substance
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