



Post Authorisation Assessments

Canigen KC Vm 01708/4492

•	28 April 2021	Change in the address of a manufacturer of an active substance.
•	22 April 2021	Change to the adverse events section of the product literature.
•	02 December 2020	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
•	02 April 2020	Change in the manufacturing process of the active substance.
•	20 August 2019	Change in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning PSUR
•	26 July 2017	Changes in the manufacturing process of the finished product.
•	21 October 2015	Change in the manufacturing process of the finished product. Addition of an alternative test procedure for the finished product.
•	25 September 2015	Change of an administration device. Changes to the package leaflet and labelling not connected with the SPC. Changes to the package leaflet and packaging connected with the SPC. Change to primary packaging.
•	03 September 2015	Changes to the SPC and package leaflet / labelling to implement the outcome of a PSUR assessment.
•	25 November 2009	Addition of a manufacturer of an active substance
•	05 February 2009	Addition of manufacturer of an active substance Minor change of manufacturing process of an active substance Addition of a manufacturer of the diluent
•	04 July 2008	Renewal
•	17 June 2008	Change of quantitative/qualitative composition of packaging
•	20 December 2007	Corrections to the Product Literature
•	01 June 2007	Submission of an updated Ph. Eur. Certificate of Suitability for an excipient from an already approved manufacturer
•	16 November 2006	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	23 March 2006	Addition of a safety warning and dosage and

		administration details
•	21 December 2005	Change of duration of immunity
•	01 July 2005	Change of test procedure performed on the finished product Addition of a manufacturer of an active substance