



Post Authorisation Assessments

Porcilis Ery Suspension for Injection for Pigs Vm 01708/4355

•	16 December 2022	The maximum batch size of E. rhusiopathiae antigen to be increased from currently registered 2000 L to 3000 L. Update of blending of finished product to include addition of a fixed amount of hydrochloric acid. To add MSD AH Danube Biotech GmbH, Krems (KRE), Austria as an additional site for production of the E. rhusiopathiae antigen. 1. Add the possibility for aseptic addition of polysorbate-80 to the main fermenter medium prior to use as alternative for addition during medium preparation. 2. Add the possibility to use purified water as alternative for water for injections (WFI) to adjust the cell content of the antigen concentrate.
•	26 November 2020	Deletion of an immediate packaging container.
•	11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
•	07 August 2020	Changes to the labelling and/or package leaflet.
•	02 June 2020	Change in the name of the MAH, from Intervet UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	10 October 2019	Change in the composition (excipients) of the finished product. Change in the manufacturing process of the active substance.
•	30 March 2015	Approval of mock-ups.
•	22 March 2012	Deletion of a manufacturer of the active substance Change of manufacturer of the finished product
•	04 November 2010	Addition of a manufacturing site for labelling and packaging
•	24 March 2009	Minor changes to the manufacture of the finished product
•	22 December 2006	Renewal
•	26 July 2006	Change of legal category from PML to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation
•	20 June 2005	Change of distributor
•	23 April 2004	Addition of a manufacturer of the active substance
•	24 October 2003	Addition of a manufacturer of an active substance
•	08 January 2003	Change of product composition

•	13 September 2002	Renewal
•	04 September 2001	Addition of distributor
•	26 July 2000	Change of address of the MAH
•	27 June 2000	Change of legal category to PML
•	03 February 2000	Addition of a pack type
•	15 June 1999	Change to minimum age
•	20 November 1998	Change to safety warnings regarding stress in pregnant animals