Veterinary Medicines Directorate

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Post Authorisation Assessments

Porcilis Ery+Parvo Suspension for Injection for Pigs

Vm 01708/4334

•	20 September 2023	Addition of alternative sterilisation method of the immediate packaging of the finished product.
•	09 January 2023	Increase in the E. rhusiopathiae antigen batch size from 2000 L to 3000 L. Minor updates in the preparation method of the finished product. Addition of MSD AH Danube Biotech GmbH, Krems, Austria as production site for E. rhusiopathiae antigen. Minor updates to the currently licensed antigen production process for E. rhusiopathiae.
•	03 September 2021	Deletion of a non-significant specification parameter of the finished product.
•	23 April 2021	Change in the address of a manufacturer used in the manufacture of the active substance.
•	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.
•	03 September 2020	Changes to the labelling and/or package leaflet. Update of the SPC.
•	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.
•	22 October 2019	Deletion of manufacturing site for an active substance. Extension of the storage period of the active substance. Change in the composition (excipients) of the finished product. Change in the manufacturing process of the active substance.
•	27 January 2016	Replacement of a test.
•	11 April 2012	Variation to update the SPC and Product Literature, as well as to make changes to the Package Leaflet.
•	22 March 2012	Variation to change the name/address of the Finished Product Manufacturer.
•	12 January 2011	Variation to replace the Parvovirus Master Seed.
•	22 September 2010	Addition of a pack size.
•	24 March 2009	Variation to update the detailed description of the product method.
•	22 January 2007	Renewal.
•	16 August 2006	Transfer of legal category from POM to POM-V. Variation

		to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	05 May 2006	Addition of an Active Substance Manufacturer.
•	20 June 2005	Change of a Distributor.
•	23 February 2004	Addition of an Active Substance Manufacturer.
•	24 October 2003	Addition of an Active Substance Manufacturer.
•	06 January 2003	Variation to remove materials of animal origin.
•	19 September 2002	Renewal.
•	04 September 2001	Addition of a Distributor.
•	26 July 2000	Change in address of the Marketing Authorisation Holder.
•	26 January 1999	Removal of a Safety Test.
•	07 July 1998	Change to product Safety Warnings.
•	16 July 1997	New Marketing Authorisation.