Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobilis Rismavac + CA126

Vm 01708/4354

•	31 August 2023	Deletion of a manufacturing site for the finished product.
•	13 June 2023	Changes to the labelling and the package leaflet which are not connected with the summary of product characteristics.
•	21 July 2022	Add 1600 ml solvent presentation. Remove Holopack, Germany and Intos, the Netherlands. Add 1200 ml solvent presentation. Store below 30°C. Shelf life: 36 months. Remove glass vial presentations. Remove polyethylene bag presentations. Change in composition.
•	30 March 2022	Changes to the labelling and package leaflet.
•	07 February 2022	Additional manufacturer of the active substance.
•	18 June 2021	Change in the address of the manufacturer of the finished product.
•	23 April 2021	Change in the address of a manufacturer used in the manufacture of the active substance.
•	22 April 2021	Change in the address of the manufacturer of the finished product.
•	15 October 2020	Change in the name of the manufacturer of the finished product.
•	03 July 2020	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	09 November 2017	Change in the name of the solvent from "Nobilis solvent CA - For cell associated Nobilis poultry vaccines" to "Solvent for cell associated poultry vaccines". Harmonisation of the solvent label.
•	15 April 2015	Replacement of a secondary packaging site of the finished product.
•	12 March 2015	Change in the manufacturing process of the active substance.
•	09 January 2015	Change in test procedure for the finished product.
•	17 September 2014	Approval of updated diluent labelling.
•	27 March 2014	Updates to the diluent labelling approved.
•	17 October 2013	Grouped variation concerning changes to the labelling/package leaflet which are not connected with the SPC.
•	22 March 2012	Variation to change the name of the manufacturer responsible for batch release of the finished product.

•	03 June 2011	Grouped variation: Addition of a manufacturing site for final product and quality control of the diluent. Update of test method for an excipient. Reduction of shelf life of the finished product. Addition of a manufacturing site for labelling/packaging. Addition of a new container for the diluent. Update of description of the production process.
•	06 December 2010	Addition of a secondary packaging site.
•	20 September 2009	Change to the in-process controls.
•	23 July 2008	Addition of an alternative manufacturer responsible for QC Testing.
•	16 June 2008	Change in the source of an excipient.
•	11 May 2007	Renewal.
•	26 July 2006	Variation to bring the SPC and labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from POM to POM-VPS. New SPC template.
•	31 January 2006	Change to the immediate packaging and method of manufacture.
•	20 June 2005	Change of Distributor.
•	05 December 2003	Renewal.
•	07 March 2002	Additional route of administration.
•	28 September 2001	Addition of a distributor.
•	13 July 2000	Change in the address of the Marketing Authorisation Holder.