

Post Authorisation Assessments

Nobilis Rismavac + CA126 Concentrate and Solvent for Suspension for Injection for Chickens Vm 06376/4125

01 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
12 December 2025	To delete a site for the manufacture of the active substance, in process control testing, blending, primary packaging and secondary packaging.
03 January 2025	Change in legal entity of the Marketing Authorisation Holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands.
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.