Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobilis Rismavac Concentrate and Solvent for Suspension for Injection for Chickens

Vm 06376/4124

05 October 2026	To make corrections to the manufacturing process and updates to starting materials. To harmonise composition of excipients. To update final product storage conditions.
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.
23 December 2025	G.I.18 update to version 3 of the national template.
18 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.
09 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. Changes to composition.
07 February 2022	Additional manufacturer of the active substance.
09 December 2021	Change in the SPC, labelling or packaging to remove references to another product. Change in the SPC, labelling or package leaflet due to new data.
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.
10 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.
11 May 2016	Approval of mock-ups.
14 April 2015	Replacement of a secondary packaging site of the finished product.
09 January 2015	Change in test procedure for the finished product.
17 September 2014	Approval of updated diluent labelling.
27 March 2014	Updated diluent labels approved.
17 October 2012	Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics.
22 March 2012	Variation to change the name of the manufacturer responsible for batch release.
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.
27 October 2009	Addition of a manufacturer responsible for QC Testing.
19 August 2008	Renewal.
16 June 2008	Change in the source of an excipient/reagent from a TSE risk to a vegetable or synthetic material.
02 August 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from POM to POM-VPS. New SPC template.
09 December 2005	Change in the shape/dimensions of the container.
20 June 2005	Change of distributor.
25 November 2004	Correction to SPC.
04 June 2004	Renewal.
12 April 2002	Amendment of combination labels.
08 October 2001	Addition of a distributor.
13 July 2000	Change in the address of a Marketing Authorisation Holder.
09 June 1999	Renewal.
17 June 1997	Change of product name from Rismavac Nobilis to Nobilis Rismavac.
02 August 1994	Addition of a manufacturer.