Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobilis Rismavac

Vm 01708/4294

•	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.