Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Nobilis Marexine CA126

Vm 01708/4289

•	02 December 2020	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
•	15 October 2020	Change in the name of the manufacturer of the finished product.
•	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.
•	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 made to the labelling and package leaflet.
•	17 October 2012	Changes to the labelling or package leaflet which are not connected with the SPC.
•	22 March 2012	Variation to change the name of the manufacturer responsible for batch release.
•	03 June 2011	Addition of a manufacturing site for final product. Change in test procedure for an excipient. Change in the shelf life of the finished product. Addition of new container for the diluent. Additional manufacturing site for labelling/packaging of the solvent.
•	06 December 2010	Addition of a secondary assembly site.
•	23 July 2008	Change in the source of an excipient from a TSE risk to a vegetable or synthetic risk.
•	02 August 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-VPS.
•	15 November 2005	Renewal.
•	21 June 2005	Change of Distributor.
•	12 April 2002	Amendment of combination labels due to additional route of administration.
•	04 September 2001	Additional Distributor in Northern Ireland.
•	25 May 2001	Renewal.
•	29 June 2000	Change in the address of a Marketing Authorisation Holder.
•	17 June 1997	Addition of a manufacturer of Active Substance and

		Dosage Form, and addition of an assembler of Dosage Form.
•	17 June 1997	Change of product name.