Veterinary Medicines Directorate

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

Post Authorisation Assessments

Nobilis Gumboro D78 Live

Vm 01708/4237

•	27 October 2021	Addition of new tests and limits applied during the manufacture of the finished product. Addition to a test procedure for the finished product. Addition to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Change in type of container for the finished product. Changes in the manufacturing process of the finished product.
•	25 June 2021	Change in the name and address of the manufacturer of the finished product.
•	12 February 2021	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
•	15 August 2018	Change in immediate packaging of the finished product. Changes in the manufacturing process of the finished product.
•	02 July 2015	Updates to the SPC and product literature.
•	28 March 2012	Change of manufacturer of the active substance
•	22 March 2012	Change of manufacturer of the finished product
•	20 November 2009	Change of name of manufacturer of excipients
•	31 July 2008	Renewal
•	17 June 2008	Addition of manufacturing site for testing
•	13 June 2007	Addition of 1,000, 2,000, 2,500, 3,000, 5,000 & 10,000 dose presentations
•	20 December 2006	Changes to the SPC and Product Literature to bring in line with new legislation Change to legal category from POM to POM-V
•	26 May 2005	Change of distributor
•	17 March 2005	Change of diluent container
•	18 February 2005	Change of finished product specification
•	04 June 2004	Renewal
•	24 July 2003	Addition of a manufacturing site for secondary packaging
•	04 September 2001	Addition of a distributor
•	13 July 2000	Change of address of the MAH
•	09 May 2000	Addition of a manufacturer of the active substance
•	06 July 1999	Renewal
•	28 January 1999	Renewal

•	09 January 1998	Change of legal category from PML to POM
•	15 July 1997	Update to licence particulars
•	17 June 1997	Change of product name from ‘Gumboro Vaccine Nobilis D78’ to ‘Nobilis Gumboro D78 Live’
•	14 June 1996	Change to formulation
•	02 August 1994	Addition of a manufacturing and assembly site of the dosage form