Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobilis IB Ma5
Vm 01708/4283

•	12 March 2024	The registration dossiers of the concerned products are supplemented with (i) the information on the use of animal derived trypsin in the manufacture of the hydrolysed gelatin and with (ii) respective extraneous agents and TSE risk assessments.
•	28 December 2022	To include the claim for associated non-mixed use of Nobilis IB Ma5 with Innovax-ND-ILT in the product information texts of Nobilis IB Ma5.
•	12 November 2021	Change in the number of units in a pack within the range of the currently approved pack sizes of the finished product. Change in the number of units in a pack within the range of the currently approved pack sizes of the finished product. Change in the number of units in a pack within the range of the currently approved pack sizes of the finished product. Addition of a secondary packaging site of the finished product. Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Addition of a manufacturing site of the finished product.
•	18 June 2021	Change in the 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.
•	22 December 2020	Change in the number of units (e.g. tablets, ampoules, etc.) in a pack within the range of the currently approved pack sizes of the finished product. Changes to the labelling and/or package leaflet.
•	15 October 2020	Change in the name of the manufacturer of the finished product.
•	30 July 2020	Change in the SPC, labelling or package leaflet due to new data.
•	12 September 2017	Addition of a supplier of packaging components or devices
•	16 August 2016	Change in the manufacturing process of the finished

		product.
•	27 June 2016	Change in test procedure for the finished product Change in test procedure for the finished product Addition of a new in-process tests and limits Change in immediate packaging of the finished product. Change in the production of the finished product.
•	20 April 2016	Change in the SPC, labelling or package leaflet due to new data.
•	14 November 2013	Updates to the labelling and approval of previously unseen mock ups.
•	28 March 2012	Change of manufacturer of the active substance.
•	22 March 2012	Change of a manufacturer of the finished product.
•	07 May 2010	Renewal.
•	30 May 2008	Addition of a manufacturing site and change to test procedure performed on the finished product.
•	01 June 2007	Submission of an updated Ph. Eur. Certificate of Suitability for an excipient.
•	31 May 2007	Update to the quality control tests.
•	10 May 2007	Addition of a 10,000 dose pack size.
•	26 July 2006	Changes to bring the SPC and Product Literature in line with new legislation and change of legal category from POM to POM-VPS.
•	12 January 2006	Addition of a manufacturer.