Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobilis ND C2 Lyophilisate for Oculonasal Suspension for Chickens

Vm 01708/3020

•	26 April 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
•	26 February 2024	To mention the use of animal derived trypsin in the manufacture of the Byco-C hydrolysed gelatin provided by Croda and to declare a change in the hydrolysis step of the gelatin (excipient) by replacing porcine trypsin by the use of either porcine or bovine trypsin.
•	14 December 2022	To correct some mistakes in the SPC and package leaflet, which were unintentionally introduced during the work-sharing procedure NL/V/xxxx/WS/027. To include the approved associated non-mixed use claim with Innovax-ND-ILT in the product information of Nobilis ND C2.
•	01 December 2021	Addition of new tests and limits applied during the manufacture of the finished product. Addition of a secondary packaging site of 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. Addition of a new container for the finished product. Changes in the manufacturing process of the finished product. Addition of a manufacturing site of the finished product.
•	08 September 2020	Change in the SPC, labelling or package leaflet due to new data.
•	17 July 2020	Change of MAH from Intervet International BV represented by: Intervet UK Ltd., Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	30 November 2018	Changes to the labelling and/or package leaflet.
•	16 February 2017	Change in the SPC, labelling or package leaflet due to new data.
•	07 April 2016	Introduction of a test procedure for the finished product. Addition of an alternative manufacturing process for the finished product.
•	20 April 2012	Variation to change the name of the manufacturer of the finished product.
•	15 May 2009	Variation to change the name of the manufacturer of the

		Active Substance.
•	30 July 2010	Renewal.
•	15 May 2009	Change in the pack size of the finished product.
•	20 March 2008	Addition of an alternative site for final product and quality control testing.
•	16 July 2007	Addition of a new TSE European Pharmacopoeia Certificate of Suitability.
•	13 June 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Change legal category from POM to POM-V.
•	27 February 2007	Change the pack size.
•	25 April 2005	New EUDE.