



Post Authorisation Assessments

Nobivac Ducat Vm 01708/3005

•	24 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.
•	23 March 2023	This variation proposes to change the product information (update SPC section 4.6), assessed by VMD and RMS. The period of assessment of the PSUR covers 1 Aug 2017 to 31 July 2020. The wording has already been agreed and this variation implements those changes. Updated to the Annotated Updated National SPC QRD Template.
•	14 February 2023	Update to Section 4.6.
•	28 May 2021	Change in the address of a manufacturer used in the manufacture of the active substance.
•	10 June 2020	Change of MAH from Intervet International BV, Represented by: Intervet UK Ltd., Walton Manor, Walton, Milton Keynes, Bucks, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	26 June 2018	Increase in batch size of active substance or intermediate used in the manufacturing process of the active substance.
•	01 June 2018	Change in the specification limits of the finished product.
•	05 January 2017	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH.
•	28 April 2016	Change in test procedure for the finished product.
•	19 February 2015	Approval of mock-ups.
•	28 November 2014	Update to the DDPS.
•	16 October 2014	To introduce PET boxes as additional secondary packaging.
•	14 January 2011	Variation concerning the addition of a Manufacturer.
•	29 May 2010	Variation to make changes to an existing pharmacovigilance system.
•	19 August 2009	European Renewal.

•	30 January 2008	Introduction of a new packaging material.
•	16 January 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2001.
•	20 November 2006	Variation concerning the addition of a Manufacturer.
•	17 May 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	18 April 2006	Addition of Manufacturing sites.
•	05 August 2005	Variation to change a finished product test procedure.
•	18 October 2004	New EUDE.