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Post Authorisation Assessments

Nobivac Tricat Trio, Lyophilisate and Solvent for Suspension for Injection for Cats Vm 01708/5070

26 February 2024 The variation is to mention the use of animal derived tryps 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 tryps in. • 23 February 2023 One-off alignment of the product information with version 9.0 of the QRD template. The PSUR covers the period from 01 July 2017 to 30 June 2020 (third 3-yearly PSUR). The data was assessed by the VMD and the RMS and subsequently product information updates were suggested. This variation implements those changes to the current SPC section 4.6. along with minor editorial changes to improve readability. • 28 May 2021 Change in the address of a manufacturer used in the manufacture of the active substance. • 14 August 2020 Change in the safety database of an existing pharmacovigilance system as described in the DDPS • 01 June 2018 Change in the safety database of an existing pharmacovigilance system as described in the DDPS • 01 June 2017 Change in test procedure for the finished product. • 28 April 2016 Change in test procedure for the finished product. • 28 April 2016 Change in test procedure for the finished product. • 13 November 2014 Approval of mock-ups. • 14 August 2015 Repeat Use Comms. • 01 June 2018 Change in test procedure for the finished product.		1	
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	•	21 October 2009	To add an additional manufacturer of the active.
	•	29 July 2009	To amend the SPC section 4.6 on adverse reactions, and update to section 4.8 to come in line with the latest

		QRD template.
•	14 January 2009	Correction/simple text layout changes to SPC and/or
		product literature.
•	09 July 2008	Variation to change reagent.
•	09 July 2008	Variation to change fill volume.
•	26 July 2007	New/Updates TSE Ph. Eur. Certificate of Suitability for
		excipient. TSE susceptible species.