Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobivac Pi, Lyophilisate and Solvent for Suspension for Injection for Dogs

Vm 01708/4632

•	February 2024	The variation is 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.
•	28 April 2023	The titration of CPi in final product to be performed automatically in addition to current manual method. Replacement of medium with bovine serum by medium without bovine serum in formulation of finished product. Deletion of the in-process control tests for sterility and mycoplasma contamination on each 5th subculture and last passage of the clean cells.
•	12 April 2022	Changes to the labelling and/or package leaflet.
•	25 February 2022	Change in the SPC, labelling or package leaflet due to new data.
•	29 December 2021	Repeat Use application to add 9 new member states.
•	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.
•	09July 2018	Change in the RMS from UK to DE.
•	01 June 2018	Change in the specification limits of the finished product.
•	30 January 2017	Update of the product literature for Nobivac Pi (SPC section 4.8 and minor changes to sections 4.9 and 6.2 plus the product leaflet section 12) following the approval of the compatibility claim for mixing of Nobivac L4 with Nobivac Pi.
•	21 October 2015	Change in test procedure for the finished product Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product
•	15 April 2015	Mock-up approval for additional secondary packaging.
•	22 January 2015	Introduction of additional secondary packaging.
•	01 September 2009	Variation to change the name and address of the Marketing Authorisation Holder.
•	08 July 2009	Addition of a production site.

•	23 December 2008	EU Renewal.
•	20 August 2008	Variation to waive the batch safety test.
•	05 December 2007	Introduction of a new packaging material.
•	31 October 2007	Addition of a Manufacturer.
•	27 June 2007	Variation to submit a new TSE European Pharmacopoeia Certificate of Suitability.
•	22 June 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	20 June 2006	Addition of a Manufacturer (blending and filling).
•	19 January 2006	Variation to comply with the Ph. Eur. Monograph 1955, identification.
•	21 July 2005	Change to finished product test procedure.
•	02 July 2004	Variation to change the product shelf-life.
•	15 May 2003	Mutual Recognition Procedure.
•	31 January 2002	New Marketing Authorisation.