Veterinary Medicines Directorate

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Post Authorisation Assessments

Canigen Pi Lyophilisate and Solvent for Suspension for Injection for Dogs

Vm 01708/4491

•	18 May 2023	Introduction of the clean cell testing for sterility and mycoplasma on each fifth subculture and last passage in the omission of IPC test. Modification of manually performed titration of CPi in final product to be performed manually or automated. Replacement of medium with bovine serum by medium without bovine serum in formulation of finished product.
•	13 December 2022	To introduce associated non-mixed use of Canigen Pi with Canigen Bb and to update SPC section 4.8 and Package Leaflet section 12 accordingly.
•	28 April 2021	Change in the address of a manufacturer of an active substance.
•	02 December 2020	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
•	11 September 2018	Correction of the composition information.
•	26 September 2017	Change in the SPC, labelling or package leaflet due to new data.
•	24 September 2015	Change in the manufacturing process of the finished product.
•	24 September 2015	Change in test procedure for the finished product.
•	26 August 2015	Introduction of plastic boxes as secondary packaging. Update to section 4.8 of the SPC. Changes to the labelling and package leaflet.
•	29 July 2009	Change of manufacturing site of the active substance
•	04 July 2008	Renewal
•	16 June 2008	Change to the quantitative/qualitative composition of the packaging
•	27 June 2007	Addition of a manufacturing site of the finished product
•	01 November 2006	Change in legal category from POM to POM-V Changes to the SPC and Product Literature
•	02 August 2006	Change of shelf life from 12 months to 29 months Change of in-use shelf life from 12 months to 24 months
•	20 July 2005	Change to test method performed on the finished product