Veterinary Medicines Directorate

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Post Authorisation Assessments

Caninsulin 40 IU/ml Suspension for Injection

Vm 01708/4244

•	14 November 2023	Variation to correct an omission in a previous procedure, addition of a site responsible for quality control testing of the finished product.
•	09 June 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: - Change in the holding time of an intermediate or bulk product.
•	24 February 2023	Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics - other changes.
•	22 September 2022	Addition of a new specification parameter. Addition of a new specification parameter. Deletion of a non-significant specification parameter. Addition of a new specification parameter. Deletion of a non-significant in-process test. Change in test procedure for the finished product. Change in the batch size of the finished product. Change in the in-use shelf life of the finished product. Change in the storage conditions of the finished product. Change in the specification parameters of the immediate packaging. Change in the specification parameters of the immediate packaging. Deletion of a non-significant in-process test. Deletion of a non-significant in-process test. Change in the manufacturing process of the finished product. Change in the specification parameters and/or limits of the finished product. Change in the specification parameters and/or limits of the finished product. Change in the specification parameters and/or limits of the finished product. Change to in-process tests or limits applied during manufacture. Change in the composition (excipient) of the finished product.
•	18 August 2022	Change in the specification parameters of the finished product.
•	25 April 2022	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	27 October 2020	Rebranding of packaging and minor SPC/QRD updates.

		Changes to the labelling and/or package leaflet.
•	20 August 2020	Minor change to an approved test procedure for an excipient
•	03 July 2020	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	14 May 2020	Change in the name of the manufacturer of the finished product.
•	03 February 2016	Change in the storage conditions after broaching; removing the non-refrigerated storage condition.
•	15 December 2014	Change to the manufacturer of the active substance. Change of ASMF holder.
•	27 March 2014	Changes to the SPC
•	25 April 2013	Deletion of manufacturing site
•	20 December 2011	Approval of previously unseen mock ups
•	15 June 2011	Additional presentation – box of 10 glass vials of 2.7ml
•	27 October 2010	Change in specification of the finished product Minor change in the manufacture of the finished product
•	16 June 2009	Change in dosage regime
•	02 April 2009	Change in test procedure performed on the finished product
•	05 November 2008	Corrections to the Product Literature
•	18 October 2007	Change of manufacturer of the active substance
•	03 May 2007	Renewal
•	01 November 2006	Change of legal category from POM to POM-V Changes to SPC and Product Literature to bring in line with new legislation
•	02 August 2006	Addition of a manufacturing site of the finished product
•	21 July 2005	Change in shelf life from 20 days to 6 weeks
•	19 May 2005	Minor change in manufacture of active substance
•	12 May 2005	Change of distributor
•	20 January 2003	Renewal
•	13 August 2001	Line-extension to include indication for cats
•	03 July 2001	Change of distributor
•	12 June 2000	Update of licence particulars
•	30 March 1999	Change of dosage particulars
•	24 December 1997	Renewal