



Post Authorisation Assessments

Caninsulin 40 IU/ml Suspension for Injection Vm 06376/4083

10 December 2024	Change in legal entity from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes MK7 7AJ to Intervet International B.V., Wim de Körverstraat, 35, 5831 AN, Boxmeer, Netherlands.
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