

VPA10996/048/001

Caninsulin 40 IU/ml Suspension for Injection

Variation	Summary	Date
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	17/02/26
Vet - B40	VNRA - Vet - B40 - Replacement or addition of a supplier of packaging components or devices - B40 Changes to the quality part of the dossier: Replacement or addition of a supplier of packaging components or devices (when mentioned in the dossier)	06/03/24
Vet - G.I.4	VRA-S - Vet - G.I.4 - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - G.I.4 Safety, Efficacy, Pharmacovigilance changes - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data.	06/02/24
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	19/10/23
Vet - B30 c)	VNRA - Vet - B30 c) - c) Addition of a new specification parameter to the specification with its corresponding test method - B30 c) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: —addition of a new specification parameter to the specification with its corresponding test method	01/09/22