

VPA10988/103/001

CANIXIN Pi/L lyophilisate and suspension for suspension for injection for dogs

Variation	Summary	Date
Vet - C10 a)	VNRA - Vet - C10 a) - - Vet - C10 a) - Changes to the labelling or the package leaflet which shall not be connected with the SPC: administrative information concerning the holder's representative	10/12/25
Vet - G.I.18	VRA-S - Vet - G.I.18 - - Vet - G.I.18 - One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	05/11/25
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17	18/06/25
Vet - F.I.a.1 c)	VRA-S - Vet - F.I.a.1 c) - c) New manufacturer of material for which an assessment is required of viral safety and/or TSE risk - F.I.a.1 c) - Quality Changes - Active Substance - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - New manufacturer of material for which an assessment is required of viral safety and/or TSE risk	03/08/23
Vet - B11 b)	VNRA - Vet - B11 b) - b) Tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance - B11 b) Changes to the quality part of the dossier: Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance — tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	24/10/22