

VPA10782/025/001

HuveGuard NB suspension for oral suspension for chickens

Variation	Summary	Date
Vet - B39	VNRA - Vet - B39 - - Vet - B39 - Change in any part of the primary packaging material not in contact with the finished product formulation (such as change of colour due to different plastic used for flip-off caps, colour code rings on ampoules or change of needle shield)	20/06/25
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	10/06/25
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	10/06/25
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	18/12/24
Vet - A1 b)	VNRA - Vet - A1 b) - b) Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier. - A1 b) Administratieve changes: Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier.	07/07/22
B.I.a.2.a	IB - B.I.a.2.a - a) Minor change in the manufacturing process of the active substance - B.I.a.2.a - QUALITY CHANGES - ACTIVE	20/06/22

	SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change in the manufacturing process of the active substance	
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