

VPA10988/105/001

Virbamec Injectable Solution 10 mg/ml

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	28/01/26
Vet - F.II.e.4 b)	VRA-R - Vet - F.II.e.4 b) - - Vet - F.II.e.4 b) - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	16/09/25
Vet - F.II.e.4 b)	VRA-R - Vet - F.II.e.4 b) - - Vet - F.II.e.4 b) - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	16/09/25
Vet - F.II.e.4 b)	VRA-R - Vet - F.II.e.4 b) - - Vet - F.II.e.4 b) - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	16/09/25
Vet - F.II.e.2 z)	VRA-R - Vet - F.II.e.2 z) - - Vet - F.II.e.2 z) Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	16/09/25
Vet - F.II.e.7 z)	VRA-R - Vet - F.II.e.7 z) - - Vet - F.II.e.7 z) - Change in supplier of packaging components or devices (when mentioned in the dossier) - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	16/09/25
Vet - B36	VNRA - Vet - B36 - Change in test procedure for the immediate packaging of the finished product (including replacement or addition) - B36 Changes to the quality part of the dossier: Change in test procedure for the immediate packaging of the finished product (including replacement or addition)	10/06/25
Vet - B39	VNRA - Vet - B39 - Change in any part of the primary packaging material not in contact with the finished product formulation - B39 Changes to the quality part of the dossier: 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)	10/06/25
Vet - G.I.15 z)	VRA-R - Vet - G.I.15 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - G.I.15 z) Safety, Efficacy, Pharmacovigilance changes - Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	11/05/25
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	23/12/24

	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	
Vet - F.II.e.4 b)	VRA-R - Vet - F.II.e.4 b) - b) Sterile medicinal products - F.II.e.4 b) Quality Changes - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	19/03/24
Vet - F.II.e.4 b)	VRA-R - Vet - F.II.e.4 b) - b) Sterile medicinal products - F.II.e.4 b) Quality Changes - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	19/03/24
Vet - F.II.e.4 b)	VRA-R - Vet - F.II.e.4 b) - b) Sterile medicinal products - F.II.e.4 b) Quality Changes - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	19/03/24
Vet - F.II.e.7 z)	VRA-R - Vet - F.II.e.7 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.e.7 z) Quality Changes - Container closure system - Change in supplier of packaging components or devices (when mentioned in the dossier) - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	19/03/24
Vet - B3 f)	VNRA - Vet - B3 f) - f) Deletion of one of the authorised bulk or final containers (including packaging of an active substance) or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form - B3 f) Changes to the quality part of the dossier: Deletion of one of the authorised bulk or final containers (including packaging of an active substance) or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form	19/03/24