

VPA10988/107/001

Virbamec Injectable Solution for Cattle, Swine and Sheep 10 mg/ml

Variation	Summary	Date
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)	03/06/25
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)	03/06/25
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	20/03/24
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.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