

VPA10983/032/001

Marbocyl 2 %w/v Solution for Injection

Variation	Summary	Date
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)	31/03/23
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	31/03/23
A.7	IA - A.7 - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*	06/04/22
B.I.d.1.a.4	IB - B.I.d.1.a.4 - 4. Extension or introduction of a re-test period/storage period supported by real time data - B.I.d.1.a.4 - QUALITY CHANGES - ACTIVE SUBSTANCE - Stability - Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Re-test period/storage period -	06/04/22
B.I.b.2.e	IB - B.I.b.2.e - e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate	06/04/22
B.I.b.2.e	IB - B.I.b.2.e - e) Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - B.I.b.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting	06/04/22

	material/intermediate	
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