

VPA10983/054/001

Marbocyl P 5 mg Tablets

Variation	Summary	Date
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 material/intermediate	06/04/22