EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Memantine Mylan

## Procedural steps taken and scientific information after the authorisation

| Application number | Scope | Opinion/ Notification [1] issued on | Commission Decision Issued[2] / amended on | Product Information affected[3] | Summary |
|---|---|---|---|---|---|
| N/0020 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 24/03/2023 | | PL | |
| N/0019 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 12/10/2022 | | PL | |

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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| II/0018 | B.I.z - Quality change - Active substance - Other variation | 22/04/2022 | n/a | | |
| T/0017 | Transfer of Marketing Authorisation | 15/09/2021 | 19/10/2021 | SmPC, Labelling and PL | |
| IA/0016 | A.7 - Administrative change - Deletion of manufacturing sites | 09/03/2021 | 26/03/2021 | Annex II and PL | |
| IA/0015 | A.7 - Administrative change - Deletion of manufacturing sites | 22/12/2020 | n/a | | |
| IB/0014 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 14/04/2020 | 26/03/2021 | SmPC and PL | |
| N/0013 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 13/03/2019 | 26/03/2021 | PL | |
| T/0012 | Transfer of Marketing Authorisation | 25/07/2018 | 10/09/2018 | SmPC, Labelling and PL | |
| IB/0011 | B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation | 30/05/2018 | n/a | | |
| R/0010 | Renewal of the marketing authorisation. | 09/11/2017 | 08/01/2018 | SmPC, Annex | Based on the review of data on quality, safety and efficacy, |

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| | | | | II, Labelling and PL | the CHMP considered that the benefit-risk balance of Memantine Mylan in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. |
| IA/0009/G | This was an application for a group of variations.<br><br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test | 23/06/2017 | n/a | | |
| IB/0008 | B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) | 17/01/2017 | 08/01/2018 | SmPC | |
| IB/0007/G | This was an application for a group of variations.<br><br>B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products<br>B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place | 07/12/2016 | n/a | | |
| IA/0006/G | This was an application for a group of variations. | 22/09/2016 | n/a | | |

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| | B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure | | | | |
| IB/0005/G | This was an application for a group of variations.<br><br>B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF<br>A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient<br>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation | 11/07/2016 | n/a | | |
| IA/0004 | A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) | 17/02/2016 | n/a | | |
| IAIN/0003 | C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV | 28/07/2015 | n/a | | |

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| | (including contact details) and/or changes in the PSMF location | | | | |
| IB/0002 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 23/06/2015 | 29/06/2016 | SmPC, Labelling and PL | |
| IAIN/0001/G | This was an application for a group of variations.<br><br>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site<br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site<br>B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place<br>B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size | 18/11/2013 | n/a | | |