# Miglustat Gen.Orph

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 |
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| IB/0024 | 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 | 13/03/2023 | | SmPC and PL | To update section 4.4, 4.6 and 5.3 in order to improve clarity following assessment of same changes for reference product. Package leaflet has been updated accordingly. |

[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/0023 | Please refer to the Recommendations section.<br><br>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation | 09/02/2023 | n/a | | Not applicable |
| R/0022 | Renewal of the marketing authorisation. | 21/07/2022 | 19/09/2022 | SmPC, Annex II, Labelling and PL | Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Miglustat Gen.Orph in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. |
| IB/0021 | B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms | 11/01/2022 | 19/09/2022 | SmPC, Labelling and PL | |
| IAIN/0020/G | This was an application for a group of variations.<br><br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site<br>B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits<br>B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing<br>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site | 01/12/2021 | 19/09/2022 | Annex II and PL | |

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| II/0018 | B.I.z - Quality change - Active substance - Other variation | 02/09/2021 | n/a | | |
| IB/0017/G | This was an application for a group of variations.<br><br>B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data<br>B.I.b.z - Change in control of the AS - Other variation | 27/08/2021 | n/a | | |
| IB/0019 | B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation | 12/08/2021 | n/a | | |
| IB/0016 | B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data | 28/01/2021 | n/a | | |
| IA/0015/G | This was an application for a group of variations.<br><br>B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer<br>B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer | 18/12/2020 | n/a | | |

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| | B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer<br>B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer | | | | |
| II/0013 | B.I.z - Quality change - Active substance - Other variation | 29/10/2020 | n/a | | |
| IB/0014/G | This was an application for a group of variations.<br><br>B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation<br>B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation | 07/10/2020 | n/a | | |
| IA/0012/G | This was an application for a group of variations.<br><br>B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place<br>B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold | 29/07/2020 | n/a | | |

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| | increase compared to the originally approved batch size | | | | |
| N/0011 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 28/05/2020 | 19/09/2022 | PL | |
| IB/0010/G | This was an application for a group of variations.<br><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>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 | 08/04/2020 | n/a | | |
| N/0009 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 03/03/2020 | 28/04/2020 | PL | |
| IA/0008 | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process | 12/12/2019 | n/a | | |
| IA/0007 | 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 | 02/10/2019 | n/a | | |
| II/0003 | B.I.a.1.b - Change in the manufacturer of AS or of a | 04/07/2019 | n/a | | |

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| | starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF | | | | |
| IB/0006 | 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) | 22/05/2019 | 28/04/2020 | SmPC | |
| IB/0005 | 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 | 26/03/2019 | 29/04/2019 | SmPC, Labelling and PL | |
| N/0002 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 02/05/2018 | 25/02/2019 | Labelling and PL | |
| IAIN/0001 | A.1 - Administrative change - Change in the name and/or address of the MAH | 02/03/2018 | 25/02/2019 | SmPC, Labelling and PL | |