# Xofluza

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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| II/0021 | C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one | 25/04/2025 | 26/05/2025 | SmPC, Annex II, Labelling and PL | |
| IA/0023 | B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the | 09/10/2024 | n/a | | |

[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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| | dossier) - Replacement or addition of a supplier | | | | |
| PSUSA/10895 /202402 | Periodic Safety Update EU Single assessment - baloxavir marboxil | 03/10/2024 | n/a | | PRAC Recommendation - maintenance |
| IB/0019 | B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) | 04/12/2023 | n/a | | |
| PSUSA/10895 /202302 | Periodic Safety Update EU Single assessment - baloxavir marboxil | 28/09/2023 | n/a | | PRAC Recommendation - maintenance |
| IB/0017/G | This was an application for a group of variations.<br><br>B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation<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 | 28/04/2023 | n/a | | |
| IB/0016/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.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<br>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change | 25/04/2023 | n/a | | |

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| | in the manufacturing process<br>B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation<br>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation<br>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site<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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation<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>A.7 - Administrative change - Deletion of manufacturing sites<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.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation<br>B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other | | | | |

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| | changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS<br>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate<br>B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation<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.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 | | | | |
| X/0008/G | This was an application for a group of variations.<br><br>Annex I_2.(d) Change or addition of a new pharmaceutical form<br>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one<br>Annex I_2.(c) Change or addition of a new strength/potency | 10/11/2022 | 10/01/2023 | SmPC, Labelling and PL | Please refer to scientific discussion Xofluza-H-C-004974-X-0008-G. |
| IB/0015/G | This was an application for a group of variations.<br><br>B.I.d.1.z - Stability of AS - Change in the re-test | 27/10/2022 | n/a | | |

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| | period/storage period or storage conditions - Other variation<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 | | | | |
| PSUSA/10895 /202202 | Periodic Safety Update EU Single assessment - baloxavir marboxil | 29/09/2022 | n/a | | PRAC Recommendation - maintenance |
| IB/0014/G | This was an application for a group of variations.<br><br>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate<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<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.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS<br>B.I.b.1.z - Change in the specification parameters | 28/09/2022 | n/a | | |

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| | and/or limits of an AS, starting material/intermediate/reagent - Other variation<br>B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation<br>B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation<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.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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation<br>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation | | | | |
| IB/0012/G | This was an application for a group of variations.<br><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.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation | 20/09/2022 | n/a | | |

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| | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process<br>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation<br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site<br>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site<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 | | | | |
| IA/0013/G | This was an application for a group of variations.<br><br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure<br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure<br>A.7 - Administrative change - Deletion of manufacturing sites | 12/08/2022 | n/a | | |
| IB/0011/G | This was an application for a group of variations.<br><br>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation | 01/08/2022 | 10/01/2023 | SmPC | |

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| | B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation<br>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)<br>B.II.f.1.b.z - Stability of FP - Extension of the shelf life of the finished product - Other variation<br>B.II.f.1.b.z - Stability of FP - Extension of the shelf life of the finished product - Other variation | | | | |
| IA/0009 | 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) | 26/04/2022 | n/a | | |
| X/0003/G | This was an application for a group of variations.<br><br>Annex I_2.(c) Change or addition of a new strength/potency<br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes | 24/02/2022 | 25/04/2022 | SmPC, Labelling and PL | |
| PSUSA/10895 /202108 | Periodic Safety Update EU Single assessment - baloxavir marboxil | 10/03/2022 | n/a | | PRAC Recommendation - maintenance |
| IB/0007 | C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation | 14/01/2022 | 25/04/2022 | SmPC and PL | |

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| IB/0005/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.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate<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<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.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS<br>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation<br>B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation<br>B.I.a.2.z - Changes in the manufacturing process of | 27/10/2021 | n/a | | |

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| | the AS - Other variation<br>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation<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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation | | | | |
| PSUSA/10895 /202102 | Periodic Safety Update EU Single assessment - baloxavir marboxil | 30/09/2021 | n/a | | PRAC Recommendation - maintenance |
| IB/0002/G | This was an application for a group of variations.<br><br>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation<br>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation<br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure<br>B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure<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<br>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change | 29/03/2021 | n/a | | |

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| | in the manufacturing process<br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site<br>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site<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 | | | | |