# Bortezomib Hospira

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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| IAIN/0024 | A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release | 06/10/2023 | | Annex II and PL | |
| IA/0022 | A.6 - Administrative change - Change in ATC Code/ATC Vet Code | 28/02/2022 | 03/02/2023 | SmPC and 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).

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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| R/0020 | Renewal of the marketing authorisation. | 25/02/2021 | 28/04/2021 | 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 Bortezomib Hospira in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. |
| IA/0021 | A.7 - Administrative change - Deletion of manufacturing sites | 02/03/2021 | 24/02/2022 | Annex II and PL | |
| PSUSA/424/202004 | Periodic Safety Update EU Single assessment - bortezomib | 10/12/2020 | 11/02/2021 | SmPC and PL | Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/424/202004. |
| IB/0018/G | This was an application for a group of variations.<br><br>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<br>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<br>C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation | 18/09/2020 | 11/02/2021 | SmPC, Annex II, Labelling and PL | |

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| IB/0015/G | This was an application for a group of variations.<br><br>B.I.z - Quality change - Active substance - 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<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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<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>A.7 - Administrative change - Deletion of manufacturing sites<br>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other | 28/02/2020 | n/a | | |

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| | 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.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol | | | | |
| N/0016 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 02/12/2019 | 11/02/2021 | PL | |
| PSUSA/424/201904 | Periodic Safety Update EU Single assessment - bortezomib | 28/11/2019 | n/a | | PRAC Recommendation - maintenance |
| N/0013 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 12/04/2019 | 11/02/2021 | PL | |
| PSUSA/424/201804 | Periodic Safety Update EU Single assessment - bortezomib | 13/12/2018 | 14/02/2019 | SmPC and PL | Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/424/201804. |
| IB/0012/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>B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of | 18/12/2018 | n/a | | |

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| | an obsolete parameter)<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.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation<br>B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF<br>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation | | | | |
| II/0008 | B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products | 08/11/2018 | 14/02/2019 | SmPC, Annex II, Labelling and PL | |
| T/0010 | Transfer of Marketing Authorisation | 17/07/2018 | 08/08/2018 | SmPC, Labelling and PL | |
| IAIN/0011 | B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing | 30/07/2018 | 14/02/2019 | Annex II and PL | |
| PSUSA/424/201704 | Periodic Safety Update EU Single assessment - bortezomib | 30/11/2017 | n/a | | PRAC Recommendation - maintenance |

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| N/0007 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 13/11/2017 | 18/01/2018 | PL | |
| II/0006/G | This was an application for a group of variations.<br><br>B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products<br>B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products | 26/10/2017 | 18/01/2018 | SmPC, Annex II, Labelling and PL | The Product Information has been updated with the inclusion of two new presentations of 2.5 mg and 3.0 mg of bortezomib powder per vial. The volume of reconstitution of the powder for the new presentations is such that the bortezomib concentration in the final solution for injection and hence the posology, computed based on body surface area is unaffected. |
| IB/0004 | 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 | 19/07/2017 | 18/01/2018 | SmPC, Annex II, Labelling and PL | |
| IA/0003 | B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information | 13/06/2017 | n/a | | |
| N/0002 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 14/02/2017 | 18/01/2018 | PL | |

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| IB/0001 | B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation | 27/01/2017 | 18/01/2018 | SmPC | |