Bortezomib SUN

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/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/01/2025		PL	
II/0023	B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms	11/07/2024	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).

	manufactured by complex manufacturing processes				
II/0022	B.I.z - Quality change - Active substance - Other variation	01/02/2024	n/a		
PSUSA/424/202304	Periodic Safety Update EU Single assessment - bortezomib	30/11/2023	n/a		PRAC Recommendation - maintenance
IAIN/0021	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	16/10/2023	n/a		
IB/0019/G	This was an application for a group of variations. 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 A.6 - Administrative change - Change in ATC Code/ATC Vet Code	31/08/2021	12/08/2022	SmPC	
IB/0018	B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	26/07/2021	n/a		
IB/0017	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)	26/07/2021	12/08/2022	SmPC	
R/0015	Renewal of the marketing authorisation.	22/04/2021	21/06/2021	SmPC, Labelling and	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of

				PL	Bortezomib Sun in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/424/202004	Periodic Safety Update EU Single assessment - bortezomib	10/12/2020	18/02/2021	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/424/202004.
IB/0016	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)	14/12/2020	21/06/2021	SmPC	
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/10/2020	18/02/2021	PL	
IB/0012	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	09/07/2020	18/02/2021	Annex II and PL	
PSUSA/424/201904	Periodic Safety Update EU Single assessment - bortezomib	28/11/2019	n/a		PRAC Recommendation - maintenance
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/08/2019	18/02/2021	PL	
IA/0010	B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)	31/07/2019	n/a		

PSUSA/424/201804	Periodic Safety Update EU Single assessment - bortezomib	13/12/2018	20/02/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/424/201804.
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/11/2018	20/02/2019	PL	
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/07/2018	20/02/2019	PL	
PSUSA/424/201704	Periodic Safety Update EU Single assessment - bortezomib	30/11/2017	n/a		PRAC Recommendation - maintenance
IB/0004	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)	07/09/2017	15/11/2017	SmPC	
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	06/07/2017	15/11/2017	SmPC and PL	
IB/0001/G	This was an application for a group of variations. 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) B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	24/11/2016	15/11/2017	SmPC, Labelling and PL	
