Voraxaze

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
IB/0022	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)	09/02/2024		SmPC	
PSUSA/10968 /202307	Periodic Safety Update EU Single assessment - glucarpidase	08/02/2024	n/a		PRAC Recommendation - maintenance

[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).

IB/0024	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	29/01/2024	n/a		
IA/0023	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	10/11/2023	n/a		
IA/0021/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	05/10/2023	n/a		
PSUSA/10968 /202301	Periodic Safety Update EU Single assessment - glucarpidase	31/08/2023	n/a		PRAC Recommendation - maintenance
IB/0019	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	31/07/2023	n/a		
IB/0018	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	07/07/2023	n/a		
S/0013	1st annual re-assessment	25/05/2023	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data

					submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of Voraxaze should be maintained.
IB/0016	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	25/04/2023	n/a		
IB/0012	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	20/03/2023	n/a		
IA/0015/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	23/02/2023	n/a		
IB/0014	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	15/02/2023	n/a		
IB/0011	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	09/02/2023	n/a		

IB/0010	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	09/02/2023	n/a		
PSUSA/10968 /202207	Periodic Safety Update EU Single assessment - glucarpidase	09/02/2023	n/a		PRAC Recommendation - maintenance
IB/0008	B.II.d.z - Change in control of the Finished Product - Other variation	02/02/2023	n/a		
IA/0009/G	This was an application for a group of variations. B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	18/01/2023	n/a		
IA/0007/G	This was an application for a group of variations.	16/12/2022	n/a		

	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 an obsolete parameter) B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier				
II/0004	B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	22/09/2022	n/a		
IB/0003/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.d.1.d - Change in the specification parameters	27/06/2022	n/a		

	and/or limits of the finished product - Deletion of a non-significant specification parameter				
II/0002	B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	28/04/2022	n/a		
IB/0001	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	03/03/2022	n/a		