EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Voraxaze

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type IA_IN /	A. ADMINISTRATIVE CHANGES - A.1 Change	05/12/2025		SmPC,	

[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).

EMA/VR/0000314574	in the name and/or address of the marketing authorisation holder - Accepted			Labelling and PL	
Variation type IB / EMA/VR/0000291658	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted	08/09/2025	N/A		
Annual reassessment - H / EMA/S/0000245171	3rd annual re-assessment.	24/07/2025			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.
Variation type IB / EMA/VR/0000282479	B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted	22/07/2025	N/A		
Variation type IB / EMA/VR/0000281027	B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	18/07/2025	N/A		
Variation type IB / EMA/VR/0000272959	B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted	13/06/2025	N/A		

Variation type IA / EMA/VR/0000265525	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	10/04/2025	N/A		