Evrenzo

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
Article 61(3) /	- Notification acc. Article 61(3) - Accepted	11/05/2026		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).

EMA/N/0000347565	Update of the package leaflet with revised contact details of local representatives.				
Renewal - 5 year / EMA/R/0000304810		29/01/2026	30/03/2026	SmPC, Annex II, Labelling and PL	
PSUR / EMA/PSUR/0000257864	In view of available data on Ischemic central nervous system vascular conditions from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship, a positive dechallenge and rechallenge and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between roxadustat and Cerebral infarction is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing roxadustat should be amended accordingly. Furthermore, based on the expressed concerns of the MAH that current information presented in the PIL on Thrombocytopenia may suggest that the symptoms listed in the section 4 may affect up to 1 in 10 people, the PRAC Rapporteur concluded that the product information of products containing roxadustat should be amended to avoid this misinterpretation.	24/07/2025	17/09/2025	SmPC and PL	Variation