



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Xydalba

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	20/11/2025		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/0000313336	Update of the package leaflet with revised contact details of local representatives.				
Article 61(3) / EMA/N/0000304870	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives.	21/10/2025		PL	
Article 61(3) / EMA/N/0000273777	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with the addition of contact details of local representatives	21/05/2025		PL	