Xaluprine

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 /	This was an application for a group of	24/09/2025		Annex II and	

[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/0000300720	variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted			PL	
Marketing Authorisation Transfer - H / EMA/T/0000287233	- Transfer of a marketing authorisation - transfer of marketing authorisation from Nova Laboratories Ireland Limited to Lipomed GmbH	24/07/2025	11/08/2025	SmPC, Labelling and PL	

Variation type IB / EMA/VR/0000254018	This was an application for a group of variations. B.IV.1 Change of a measuring or administration device - B.IV.1.z Other variation - Accepted B.IV.1 Change of a measuring or administration device - B.IV.1.z Other variation - Accepted B.IV.1 Change of a measuring or administration device - B.IV.1.z Other variation - Accepted B.IV.1 Change of a measuring or administration device - B.IV.1.z Other variation - Accepted B.IV.1 Change of a measuring or administration device - B.IV.1.z Other variation - Accepted B.IV.1 Change of a measuring or administration device - B.IV.1.z Other variation - Accepted B.IV.1 Change of a measuring or administration device - B.IV.1.z Other variation - Accepted B.IV.1 Change of a measuring or	18/03/2025	N/A		

	administration device - B.IV.1.z Other variation - Accepted				