PREVYMIS

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	05/12/2025		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/0000304418	Update of the package leaflet with revised contact details of local representative and update of the Use of Instructions to remove the word 'child' from 'step 10. Take all of the PREVYMIS mixture' under 'Mix with soft food'.				
Variation type IB / EMA/VR/0000262178	This was an application for a group of variations. B.II.g.5 Implementation of changes foreseen in an approved change management protocol - B.II.g.5.b The implementation of the change requires further supportive data - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.g Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue - Accepted	15/04/2025		Annex II	
PSUR / EMA/PSUR/0000248461	- -				Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing letermovir remains unchanged and therefore recommends the maintenance of the marketing authorisation(s). Issues to be addressed in the next PSUR or as a

					post-authorisation measure (PAM) or as part of a subsequent RMP update