Lopinavir/Ritonavir Viatris

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 /	This was an application for a group of	05/09/2025		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/0000291122	variations. B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted			PL	
Variation type IB / EMA/VR/0000268655	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC)	10/07/2025	N/A		

	No 1234/2008. B.II.e) Container closure system - B.II.e.z Other variation - Accepted				
Article 61(3) / EMA/N/0000256687	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representative and deletion of 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4.	26/03/2025		PL	
Marketing Authorisation Transfer - H / EMA/T/0000178558	- Transfer of a marketing authorisation - Accepted Transfer of Marketing Authorisation from Mylan Pharmaceuticals Limited to Viatris Limited.	31/05/2024	29/07/2024	SmPC, Labelling and PL	
Variation type IA_IN / EMA/VR/0000174634	A.2 Change in the (invented) name of the medicinal product - A.2.a) for Centrally Authorised products - Accepted	18/04/2024	13/06/2024	SmPC, Labelling and PL	