# Lopinavir/Ritonavir Viatris

Procedural steps taken and scientific information after the authorisation

| Application number | Scope | Opinion/ Notification [1] issued on | Commission Decision Issued [2] / amended on | Product Information affected [3] | Summary |
|---|---|---|---|---|---|
| Article 61(3) / EMA/N/0000256687 | - Notification acc. Article 61(3) - Update of the package leaflet with revised contact details of local representative and | 26/03/2025 | | 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).

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| | deletion of 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4. | | | | |
| Marketing Authorisation Transfer - H / EMA/T/0000178558 | - Transfer of a marketing authorisation - Accepted<br><br>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 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>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 | |