



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Darunavir Viatrix

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 /	E.4 Change in the name and/or address of	05/05/2026		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/0000325156	the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.b) The change in the name and/or address concerns a manufacturer(s) whose activities include batch release of the finished product - Accepted			PL	
Article 61(3) / EMA/N/0000315580	- 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.	04/12/2025		PL	
Variation type IB / EMA/VR/0000286659	B.II.e) Container closure system - B.II.e.z Other variation - Accepted	31/07/2025			
Variation type IB / EMA/VR/0000274724	This was an application for a group of variations.	21/07/2025			

	<p>B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Accepted</p> <p>B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Accepted</p> <p>B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Accepted</p>				
Variation type IA / EMA/VR/0000280786	A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted	24/06/2025			
Variation type IB / EMA/VR/0000254721	B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	18/03/2025			

Variation type IA_IN / EMA/VR/0000230157	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	03/10/2024			
Marketing Authorisation Transfer - H / EMA/T/0000178554	Transfer of Marketing Authorisation from Mylan Pharmaceuticals Limited to Viatris Limited.	31/05/2024	05/07/2024	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	