Kaletra

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 II /	This was an application for a variation	18/09/2025	30/10/2025	SmPC and PL	In situations when lopinavir/ ritonavir doses above

[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/0000278292	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.2 and 4.5 of the SmPC in order to reduce the MDD of Kaletra /Aluvia tablets to 400/100 mg twice a day (reducing the MDD of the ritonavir component to 200 mg), when co-administered with efavirenz and nevirapine, and to recommend dosing with the lopinavir/ritonavir oral solution formulation where Kaletra/Aluvia tablet dosing of 500 mg/125 mg twice daily is required. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.				400/100 mg twice daily are warranted, such as during co-administration with efavirenz or nevirapine, the oral solution formulation should be used instead of tablets. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000256269	This was an application for a group of variations. B.II.f.1.a Reduction of the shelf life of the finished product - B.II.f.1.a.1 As packaged for sale - Accepted	09/04/2025	30/10/2025	SmPC, Labelling and PL	

	B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.3 Deletion of an immediate packaging container that does not lead to the complete deletion of a strength or pharmaceutical form - Accepted				