

Norvir

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 group of	18/09/2025	03/11/2025	SmPC and PL	Please refer to Scientific Discussion 'Norvir-H-C-

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.

³ SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



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.

EMA/VR/0000249795	variations.	000127-II-EMA/VR/000024979!
	C.I.6 Change(s) to therapeutic indication(s)	
	- C.I.6.a Addition of a new therapeutic	
	indication or modification of an approved one	
	- Accepted	
	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	
	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	
	A grouped application consisting of Type II	
	A grouped application consisting of: Type II (C.I.6.a): To modify the approved	
	therapeutic indication to reflect current	
	clinical use as a pharmacokinetic enhancer of	
	other antiretroviral products only.	
	Consequently, sections 4.1, 4.2, 4.3, 4.4,	
	4.5, 4.8 and 5.1 of the SmPC and the	
	Package Leaflet are updated accordingly.	
	The updated RMP version 8.0 has also been	
	submitted. In addition, the MAH took the	
	opportunity to implement editorial changes	
	to the PI. Type IB (B.II.f.1.a.1): To reduce	
	the shelf life of Norvir 100 mg powder for	
	oral suspension as packaged for sale, from	
	36 months to 18 months and to reduce the	
	shelf-life of Norvir 100 mg film-coated tablet	

from 2 years to 18 months. Type IB
(B.II.f.1.e): To change the stability protocol
of Norvir 100 mg powder for oral suspension
to reflect updated long term testing intervals
as a consequence of the reduction in shelf
life. The group of variations leads to
amendments to the annexes I and IIIB, and
to the RMP.