Delstrigo

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 /	C.I HUMAN AND VETERINARY MEDICINAL	16/10/2025		SmPC and PL	As a result of this variation, section 4.8 of the SmPC

[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/0000267948	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 section 4.8 of the SmPC to add a note regarding the adverse reaction 'hepatitis' based on post marketing data and literature. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.				of Delstrigo was updated with a footnote to the Adverse Reactions table and the listed term hepatitis: " †This adverse reaction was not identified as an adverse reaction associated with doravirine from the Phase 3 clinical studies (DRIVE-FORWARD, DRIVE-AHEAD, DRIVE-SHIFT), but was seen during post-marketing use of doravirine-containing regimens and is an adverse reaction listed in the SmPC of 3TC and TDF. The highest frequency category reported in the 3TC and TDF SmPCs is used." For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000293703	B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.g Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue - Accepted	15/09/2025	N/A		
Variation type II / EMA/VR/0000247253	C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Other variation - Accepted	08/05/2025		SmPC and PL	New SmPC text The section 4.4 of the SmPC was updated to amend an existing warning on bone effects. The section 4.8 of the SmPC was updated to add 'bone mineral density decreased' to the list of adverse drug reactions (ADRs) with frequency 'common'. For more information, please refer to the Summary of Product Characteristics.

	Update of sections 4.4, and 4.8 of the SmPC in order to amend an existing warning on bone effects and add ‘bone mineral density decreased’ to the list of adverse drug reactions (ADRs) with frequency 'common' following PRAC recommendation for Viread PSUSA 00002892-202303; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet.				