Emtricitabine/tenofovir disoproxil Krka d.d.

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, please 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
Article 61(3) /	- Notification acc. Article 61(3) -	31/01/2025		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).

EMA/N/0000242563	Update of the package leaflet with revised details of a local representative and to delete United Kingdom (Northern Ireland) from the list of local representatives in line with QRD template v10.4. Additionally, the MAH took the opportunity to introduce minor corrections to the RO labelling text and package leaflet to align with the EN text.				
Variation type IB / EMA/VR/0000176720	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted To update section 4.4 of the SmPC to amend a warning/precaution regarding bone effects. Update of section 4.8 of the SmPC to add the adverse reaction bone mineral density decreased with a frequency common. The package leaflet has been updated accordingly. Further more the MAH has taken the opportunity to make minor correction to align with the reference product or QRD.	11/06/2024		SmPC and PL	