



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Emtricitabine/Tenofovir disoproxil Mylan

Procedural steps taken and scientific information after the authorisation*

*Due to Agency`s update of its procedure management systems, an additional document, capturing the historical lifecycle may be available in the 'Assesment history' section. For the complete 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
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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).



Variation type IB /
EMA/VR/0000175866

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. In addition, the MAH has updated the list of local representatives for ES, PL, CY, AT, IE and IT and minor correction have been made to the translations for consistency.

11/06/2024

SmPC and PL