# Emtricitabine/Tenofovir disoproxil Zentiva

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 |
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| Variation type IB / | Outcome: | 03/09/2026 | | | |

[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).

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| EMA/VR/0000335678 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted<br><br>To update the RMP in line with the reference medicinal product:  To remove missing Information Safety in pregnancy and lactation. To add Annex 4: Specific Adverse Reaction Follow-up Questionnaire for Lack of efficacy in pre-exposure prophylaxis. And to remove Follow-up form for renal toxicity, Follow-up form for renal tubulopathy, Follow-up form for bone events, Pregnancy report form (to report pregnancy before outcome is known) and Pregnancy outcome report (to be used when pregnancy outcome is known). | | | | |

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| Variation type IA_IN / EMA/VR/0000339625 | Outcome:<br>Q.II.b.1 Change in the manufacturing site for part or all of the manufacturing process of the finished product (except for batch release and batch control testing sites) - Q.II.b.1.a) Addition or replacement of a site responsible for secondary packaging - Accepted | 16/04/2026 | | | |
| Article 61(3) / EMA/N/0000256683 | Outcome:<br>- Notification acc. Article 61(3) - Accepted<br><br>Update of the package leaflet with revised contact details of local representative and deletion of 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4. | 18/03/2025 | | PL | |