Capecitabine Teva

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 IB /	C.I.2 Change(s) in the Summary of Product	10/07/2025		SmPC,	To update Section 4.4 of the SmPC to amend a

[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/0000282000	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 C.I.2.a (Type IB) – To update Section 4.4 of the SmPC to amend a warning on phenotyping for DPD deficiency. The change follows assessment of the same change for the reference product, Xeloda. In addition, the MAH took the opportunity to implement editorial changes, including updates throughout the PI to align with the QRD template, the correction of typographical errors, the translation of the INN from Latin to CZ for the CZ PI in accordance with the requirements of the CZ competent authority, the amendment of the contact details for the local representative in ES, and the removal of the local representative for the United Kingdom (Northern Ireland), in line with the QRD template.			Labelling and PL	warning on phenotyping for DPD deficiency. The change follows assessment of the same change for the reference product, Xeloda.