Olanzapine 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, 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
Variation type IB /	This was an application for a group of	12/05/2025		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/0000256216	variations. B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.1 Solid, semi-solid and non-sterile liquid pharmaceutical forms - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.1 Solid, semi-solid and non-sterile liquid pharmaceutical forms - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.1 Solid, semi-solid and non-sterile liquid pharmaceutical forms - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.1 Solid, semi-solid and non-sterile liquid pharmaceutical forms - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.1 Solid, semi-solid and non-sterile liquid pharmaceutical forms - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted			Labelling and PL	

	B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted				
Variation type IA / EMA/VR/0000221290	A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted	29/08/2024		SmPC, Annex II, Labelling and PL	