Tolucombi

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 /	This was an application for a group of	19/06/2025		SmPC and PL	Update section 4.4 and 4.8 of the SmPC to added

[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/0000242380	variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon - Accepted C.I.z Update section 4.4 and 4.8 of the SmPC to added new safety information regarding intestinal angioedema. The package leaflet was update accordingly. C.I.2.a Update of sections 4.2, 4.3 (anuria), 4.4 (hyponatremia), 4.5 (iodinated contrast products), 4.6 (fertility), 4.7 (syncope, vertigo), 4.8 (combined table of ADR) and				new safety information regarding intestinal angioedema. The package leaflet was update accordingly. Update of sections 4.2, 4.3 (anuria), 4.4 (hyponatremia), 4.5 (iodinated contrast products), 4.6 (fertility), 4.7 (syncope, vertigo), 4.8 (combined table of ADR) and 5.2 (renal impairment) of the SmPC in order to align with reference labels for both active substances. The Package Leaflet is updated accordingly. In addition the MAH has taken to opportunity to update the annexes in line with QRD version 10.4 and to update the list of local representatives.

	5.2 (renal impairment) of the SmPC in order to align with reference labels for both active substances. The Package Leaflet is updated accordingly. In addition the MAH has taken to opportunity to update the annexes in line with QRD version 10.4 and to update the list of local representatives.				