



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Tolura

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 /	C.I HUMAN AND VETERINARY MEDICINAL	18/03/2025		SmPC and PL	To updated sections 4.4 and 4.8 of the SmPC to add

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/0000247066	<p>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 change(s) which require to be further substantiated by new additional data to be submitted by the MAH - Accepted</p> <p>To updated sections 4.4 and 4.8 of the SmPC to add new safety information regarding intestinal angioedema following PRAC recommendation EMA/PRAC/499603/2024; EPITT 20104. The package leaflet is updated accordingly. In addition the MAH has taken the opportunity to make minor editorial corrections in several translations.</p>				<p>new safety information regarding intestinal angioedema following PRAC recommendation EMA/PRAC/499603/2024; EPITT 20104. The package leaflet is updated accordingly. In addition the MAH has taken the opportunity to make minor editorial corrections in several translations.</p>
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