Tuzulby

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 /	Outcome:	12/08/2026		SmPC and PL	

[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/0000361747	C.3 Change(s) in the summary of product characteristics, labelling or package leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or following the assessment of an Urgent Safety Restriction etc.) - C.3.b) Implementation of the agreed wording that requires additional minor assessment (e.g. translations are not yet agreed upon) - Accepted To update the SmPC section 4.8 adding Epistaxis with the frequency "not know" following the outcome of EMEA/H/C/PSUSA/00002024/202110. The PL is updated accordingly.				
Variation type IB / EMA/VR/0000314054	Outcome: 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	19/12/2025		SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000303608	Outcome: C.I.3 Change(s) in the Summary of Product	04/11/2025		SmPC and PL	To update Sections 4.4 and 4.8 of the SmPC and Sections 2 and 4 of the PL to implement the

	Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Implementation of wording agreed by the competent authority + QRD update - Accepted C.I.3.z (Type IB) - To update Sections 4.4 and 4.8 of the SmPC and Sections 2 and 4 of the PL to implement the wording agreed by the PRAC following the outcome of the PSUR procedure EMEA/H/C/PSUSA/00002024/202410. In addition, the MAH took the opportunity to implement editorial changes to update the contact details of the local representatives in NL and AT. Furthermore, the PI in DE was updated to correct typographical errors, the PI in FI was updated to correct a translation error in Section 4.4 of the SmPC, and the PI in DK was updated to correct the term used for the pharmaceutical form, following a request from the Danish authority.				wording agreed by the PRAC following the outcome of the PSUR procedure EMEA/H/C/PSUSA/00002024/202410.
Variation type IB / EMA/VR/0000286644	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted	08/08/2025			

	C.I.z - to submit the updated ERA Report following commitment of Day-195.				