



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Accofil

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.2 Change(s) in the Summary of Product	15/05/2025		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/0000247287	<p>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</p> <p>C.I.2.a (IB) - To update section 4.8 of the SmPC and section 4 of the Package Leaflet to add "Extramedullary hematopoiesis" as an adverse reaction with a frequency of "rare", following approval of the same changes in the reference product. Furthermore, the Marketing Authorisation Holder has taken the opportunity to introduce editorial changes to the Product Information in order to align with the reference product and correct typographical errors in the local texts for DA, ET, EL, ES, IT, PT, and RO.</p>				
Variation type IB / EMA/VR/0000256495	<p>B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted</p> <p>B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted</p>	04/04/2025	N/A		

