Yesafili

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
Article 61(3) /	- Notification acc. Article 61(3) - Accepted	25/02/2026		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/N/0000326677	Update of the package leaflet with revised contact details of local representatives.				
Variation type IA / EMA/VR/0000323979	This was an application for a group of variations. B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.b Change that does not affect the product information - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active	03/02/2026			

	substance - B.I.a.4.a Tightening of in-process limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Accepted				
Variation type IB / EMA/VR/0000317223	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted	13/01/2026		SmPC	
Variation type II / EMA/VR/0000295824	B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.f Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product - Accepted	27/11/2025			Not applicable
Variation type IB / EMA/VR/0000293312	B.II.f.1.a Reduction of the shelf life of the finished product - B.II.f.1.a.1 As packaged for sale - Accepted	25/09/2025		SmPC	

Variation type IB / EMA/VR/0000291049	B.I ACTIVE SUBSTANCE - B.I.z Other variation - Accepted	13/08/2025			
Variation type IA / EMA/VR/0000280967	This was an application for a group of variations. 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 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 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	14/07/2025			

	dossier)* - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification				

	parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted				
Variation type IB / EMA/VR/0000278069	B.I ACTIVE SUBSTANCE - B.I.z Other variation - Accepted	26/06/2025			
Variation type IB / EMA/VR/0000275575	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted	23/06/2025			
Variation type II / EMA/VR/0000245097	This was an application for a group of variations. B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of	05/06/2025		SmPC, Annex II, Labelling and PL	The SmPC and Annex II (Additional risk minimisation measures) has been updated to reflect the new presentation pre-filled syringe.

	the test methods performed at the site is a biological/immunological method - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.c Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.c Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.2 Sterile medicinal products and biological/ immunological medicinal products - Accepted				

Variation type IB / EMA/VR/0000265998	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.2.a - To update section 4.8 of the SmPC in order to add 'scleritis' to the list of adverse drug reactions (ADRs) with a frequency of '0.2 cases per 1 million injections' based on pharmacovigilance data, following assessment of the same change for the reference product. The PL is updated accordingly. In addition, the MAH took the opportunity to add warnings for polysorbate into the SmPC and the PL in line with the EC Excipient Guideline. Furthermore, the MAH took the opportunity to introduce editorial changes to the PI for HR, HU and IS to align with the reference product PI.	12/05/2025		SmPC and PL	To update section 4.8 of the SmPC in order to add 'scleritis' to the list of adverse drug reactions (ADRs) with a frequency of '0.2 cases per 1 million injections' based on pharmacovigilance data, following assessment of the same change for the reference product. The PL is updated accordingly. In addition, the MAH took the opportunity to add warnings for polysorbate into the SmPC and the PL in line with the EC Excipient Guideline.
Variation type IB / EMA/VR/0000246009	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	13/03/2025		SmPC and PL	

	submitted by the MAH - Accepted C.I.2.a (IB) - To update the Product Information to update section 4.6 of the SmPC and section 2 of the Package Leaflet to modify the current wording regarding breastfeeding, following approval of the same changes in the reference product. Furthermore, the Marketing Authorisation Holder has taken the opportunity to introduce minor editorial changes in line with the reference product in translations DA, EL, FR, HR, HU and LV.				