ALTUVOCT

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 IA /	Outcome:	03/07/2026		Annex II	

[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/0000357949	E.4 Change in the name and/or address of the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.c) The change in the name and/or address does not concern a manufacturer(s) whose activities include batch release of the finished product nor the marketing authorisation holder - Accepted				
PSUR / EMA/PSUR/0000311177	EURD: PSUSA/00011062/202508 Active substance: efanesoctocog alfa Outcome: Variation In view of available data on risk from the literature, spontaneous reports including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between efanesoctocog and Factor VIII inhibition is at least a reasonable possibility. Accordingly, the PRAC concludes that the product information of products containing efanesoctocog should be	26/03/2026	21/05/2026	SmPC and PL	Variation

	amended.				
Variation type II / EMA/VR/0000272231	Outcome: This was an application for a group of variations. B.I.b) Control of active substance - B.I.b.z Other variation - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted	29/01/2026			
PSUR / EMA/PSUR/0000274459	EURD: PSUSA/00011062/202502 Active substance: efanesoctocog alfa Outcome: Variation In view of available data on hypersensitivity reactions from spontaneous reports, including in some cases a close temporal relationship, a positive de-challenge and/or	16/10/2025	12/12/2025	SmPC and PL	Variation

	re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between efanesoctocog alfa and hypersensitivity reactions including anaphylaxys is at least a reasonable possibility. The PRAC concluded that the product information of products containing efanesoctocog alfa should be amended accordingly.				
Variation type II / EMA/VR/0000269780	Outcome: B.II.g) Design Space and post approval change management protocol - B.II.g.2 Introduction of a post approval change management protocol related to the finished product - Accepted	24/07/2025			
Variation type IB / EMA/VR/0000269881	Outcome: B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z Other variation - Accepted	30/06/2025			
Variation type IA_IN / EMA/VR/0000261918	Outcome: This was an application for a group of	08/04/2025			

	variations. B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted B.IV.1.a Addition or replacement of a device which is not an integrated part of the primary packaging - B.IV.1.a.1 Device with CE marking - 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.a Secondary packaging site - Accepted				
Variation type IB / EMA/VR/0000255925	Outcome: B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	18/03/2025			