Nplate

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 II /	B.II.b.3 Change in the manufacturing	02/10/2025			

[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/0000287291	process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.c The product is a biological/immunological medicinal product and the change requires an assessment of comparability - Accepted				
Variation type II / EMA/VR/0000276333	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.8 of the SmPC in order to remove language regarding the testing for suspected neutralizing antibodies (Immunogenicity) following RMP update in EMEA/H/C/000942/II/0091.	04/09/2025		SmPC	SmPC new text In Section 4.8 in the paragraph on Immunogenicity the following sentence is added replacing all information regarding the testing for suspected neutralizing antibodies which is now removed: "As with all therapeutic proteins, there is a potential for immunogenicity." For more information, please refer to the Summary of Product Characteristics.
Variation type IA_IN / EMA/VR/0000275010	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	27/05/2025	N/A		
Variation type II / EMA/VR/0000226893	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted	13/02/2025		SmPC and PL	Update of sections 4.4 and 4.8 of the SmPC in order to update the warning on thrombotic/thromboembolic complications and update the frequency of 'deep vein thrombosis' in the list of adverse drug reactions (ADRs) from 'uncommon' to 'common', based on a

	Update of sections 4.4 and 4.8 of the SmPC in order to update the warning on thrombotic/thromboembolic complications and update the frequency of 'deep vein thrombosis' in the list of adverse drug reactions (ADRs) from 'uncommon' to 'common', based on a comprehensive safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the wording pertaining to bone marrow aspirate and/or biopsy in patients over 60 years of age to be consistent with current standards and international guidelines for immune thrombocytopenia (ITP) diagnosis and management and to introduce minor editorial changes to the PI and update the list of the local representatives in the Package Leaflet.				comprehensive safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the wording pertaining to bone marrow aspirate and/or biopsy in patients over 60 years of age to be consistent with current standards and international guidelines for immune thrombocytopenia (ITP) diagnosis and management and to introduce minor editorial changes to the PI and update the list of the local representatives in the Package Leaflet.