Naveruclif

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 /	B.II.f.1.b Extension of the shelf life of the	11/08/2025		SmPC	

[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/0000287045	finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted				
Variation type IA_IN / EMA/VR/0000290057	This was an application for a group of variations. B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not	04/08/2025	N/A		

	affect the properties of the finished product - Accepted B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted				
Variation type IB / EMA/VR/0000279697	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 (IB) – To update section 4.6 of the SmPC based on the Reproductive Toxicity	27/06/2025		SmPC and PL	To update section 4.6 of the SmPC based on the Reproductive Toxicity Testing and Labeling recommendations, Food and Drug Administration Guidance (May 2019) and the Non-clinical Working Party/Non-clinical Working Party (S/Nc), European Medicines Agency recommendations (March 2023) on the duration of contraception following the end of treatment with a genotoxic drug. The Package Leaflet is updated accordingly. The change follows assessment of the same change for the reference

	Testing and Labeling recommendations, Food and Drug Administration Guidance (May 2019) and the Non-clinical Working Party/Non-clinical Working Party (S/Nc), European Medicines Agency recommendations (March 2023) on the duration of contraception following the end of treatment with a genotoxic drug. The Package Leaflet is updated accordingly. The change follows assessment of the same change for the reference product, Abraxane.				product, Abraxane.
Variation type IB / EMA/VR/0000277911	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	20/06/2025	N/A		
Variation type IA_IN / EMA/VR/0000276235	This was an application for a group of variations. B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.1 New certificate from an already approved manufacturer - Accepted B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.3 New certificate from a new manufacturer (replacement or	16/06/2025	N/A		

	addition) - Accepted				
Variation type IA_IN / EMA/VR/0000258150	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 B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted	12/03/2025	N/A	Annex II and PL	

	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - 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				