Apexelsin

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	10/06/2025		SmPC and PL	To update section 4.6 of the SmPC based on the

[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/0000272569	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 4.6 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 PL is updated accordingly. The change follows assessment of the same change for the reference product, Abraxane.				duration of contraception following the end of treatment with a genotoxic drug. The PL is updated accordingly. The change follows assessment of the same change for the reference product, Abraxane.
Variation type IA_IN / EMA/VR/0000268218	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	30/04/2025	N/A		

Variation type IB / EMA/VR/0000253467	B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	17/03/2025	N/A		
Variation type IA / EMA/VR/0000244612	This was an application for a group of variations. 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 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 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	15/01/2025			