Pazenir

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 /	C.I.2 Change(s) in the Summary of Product	19/06/2025		SmPC, Annex	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/0000278406	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 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 changes follow assessment of the same changes for the reference product, Abraxane. Additionally, the MAH has taken the opportunity to introduce editorial changes throughout the Product Information to align with the QRD template, to align the information on excipients, to update the contact information for the local representative for ES and to remove the local representative for UK (NI) in line with the QRD template.			II, Labelling and PL	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 changes follow assessment of the same changes for the reference product, Abraxane.

Variation type IB / EMA/VR/0000235953	This was an application for a group of variations. B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.c Deletion of a non-significant in-process test - 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	05/12/2024	N/A		
Variation type IA / EMA/VR/0000221290	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	29/08/2024		SmPC, Annex II, Labelling and PL	