Zolsketil pegylated liposomal

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_IN /	C.3 Change(s) in the summary of product	15/04/2026		SmPC and PL	To update sections 4.8 of the SmPC to implement

[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/0000340547	characteristics, labelling or package leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or following the assessment of an Urgent Safety Restriction etc.) - C.3.a) Implementation of the agreed wording - Accepted				the signal recommendation on Pegylated liposomal doxorubicin – Renal-limited thrombotic microangiopathy (EPITT no 20193) with the frequency "unknown". The package leaflet is updated accordingly.
Variation type IB / EMA/VR/0000323300	This was an application for a group of variations. B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - 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 B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.c Deletion of a test procedure if an alternative test procedure is already authorised - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product	24/02/2026			

	- B.II.e.3.c Deletion of a test procedure if an alternative test procedure is already authorised - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.c Deletion of a test procedure if an alternative test procedure is already authorised - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.c Deletion of a test procedure if an alternative test procedure is already authorised - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.c Deletion of a test procedure if an alternative test procedure is already authorised - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.c Deletion of a test procedure if an alternative test procedure is already authorised - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.c Deletion of a test procedure if an alternative test procedure is already authorised - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.c Deletion of a test procedure if an alternative test procedure is already				

	authorised - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.c Deletion of a test procedure if an alternative test procedure is already authorised - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.c Deletion of a test procedure if an alternative test procedure is already authorised - Accepted B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.a Minor changes to an approved test procedure - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Accepted				
Variation type IB / EMA/VR/0000302764	This was an application for a group of variations. B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Refused	18/12/2025			

	B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.a Minor changes to an approved test procedure - Refused B.II.e.3 Change in test procedure for the immediate packaging of the finished product - B.II.e.3.b Other changes to a test procedure (including replacement or addition) - Accepted				
Variation type IA_IN / EMA/VR/0000258184	This was an application for a group of variations. B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - 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 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	12/03/2025		Annex II and PL	

	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 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					