



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Trepulmix

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 Change in the shelf-life or storage	30/07/2025		SmPC and PL	

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/0000284407	conditions of the finished product - B.II.f.1.z Other variation - Accepted				
Variation type IB / EMA/VR/0000265482	<p>This was an application for a group of variations.</p> <p>B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted</p> <p>B.I.b) Control of active substance - B.I.b.z If information on the level of testing performed by the FP manufacturer on receipt of the AS batches is already present in the approved registration dossier, the applicant is advised to apply for a Type IB (B.I.b.z) variation to remove this information from the dossier. - Accepted</p>	26/05/2025	N/A		
Article 61(3) / EMA/N/0000261398	<p>- Notification acc. Article 61(3) -</p> <p>Update of the package leaflet with revised contact details of local representatives.</p>	10/04/2025		PL	
Variation type IB / EMA/VR/0000253556	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	19/03/2025	N/A		

	non-significant in-process test - Accepted				
Variation type IA / EMA/VR/0000246075	<p>This was an application for a group of variations.</p> <p>B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.a Tightening of in-process limits - Accepted</p> <p>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</p> <p>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</p> <p>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</p> <p>B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the</p>	30/01/2025	N/A		

	<p>finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted</p> <p>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</p> <p>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 - Refused</p>				
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