Memantine Merz

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 /	This was an application for a group of	19/06/2025		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/0000248882	variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.h Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.b Deletion of a test procedure if an alternative method is already authorised - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.b Deletion of a test procedure if an alternative method is already authorised - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.b Deletion of a test procedure if an alternative method is already authorised - Accepted				

	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.b Deletion of a test procedure if an alternative method is already authorised - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.z Other changes - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.z Other changes - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.f To reflect compliance with the Ph.Eur. and remove reference to the outdated internal test method and test method number - Accepted				

Variation type IB / EMA/VR/0000248884	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.1.a Qualitative and quantitative composition - B.II.e.1.a.1. Solid pharmaceutical forms - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	22/05/2025	N/A		