Dimethyl fumarate Mylan

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
Article 61(3) /	Outcome:	21/07/2026		Labelling and	

[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/N/0000362350	- Notification acc. Article 61(3) - Accepted Update to labelling (Annex IIIA) to align the grey-shaded text and PIL text with the current approved Product Information mock-up/specimen layout.			PL	
Variation type IA_IN / EMA/VR/0000326802	Outcome: E.4 Change in the name and/or address of the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.b) The change in the name and/or address concerns a manufacturer(s)whose activities include batch release of the finished product - Accepted	08/06/2026		Annex II and PL	
Marketing Authorisation Transfer - H / EMA/T/0000335043	Outcome: Transfer of Marketing Authorisation from Mylan Ireland Limited to Mylan Pharmaceuticals Limited	25/03/2026	23/04/2026	SmPC, Labelling and PL	

Variation type IB / EMA/VR/0000247445	Outcome: This was an application for a group of variations. B.II.a.3 Changes in the composition (excipients) of the finished product - B.II.a.3.z Other changes - Accepted B.II.a.2 Change in the shape or dimensions of the pharmaceutical form - B.II.a.2.b Gastro-resistant, modified or prolonged release pharmaceutical forms and scored tablets intended to be divided into equal doses - Accepted	12/05/2025	23/04/2026	SmPC	
Variation type IA / EMA/VR/0000257513	Outcome: A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted	10/03/2025			
Variation type IB / EMA/VR/0000246956	Outcome: C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet	13/02/2025	23/04/2026	SmPC and PL	

	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 4.8 of the SmPC and section 4 of the Package Leaflet to change the frequency category of the adverse event "Drug-induced liver injury" from "Not Known" to "Rare", following assessment of the same change for the reference product. Furthermore, the Marketing Authorisation Holder has taken the opportunity to introduce minor editorial changes.				