EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Dimethyl fumarate Accord

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 /	This was an application for a group of	25/08/2025		Annex II 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/VR/0000292854	variations. 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 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			PL	
Variation type IB / EMA/VR/0000253311	C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted To bring the RMP in line with the RMP of the reference product by e.g. removing the important identified risks; decreases in leukocyte and lymphocyte counts and drug induced liver injury.	13/03/2025	N/A		To bring the RMP in line with the reference product by e.g. removing the important identified risks; decreases in leukocyte and lymphocyte counts and drug induced liver injury.
Variation type IB / EMA/VR/0000247229	This was an application for a group of variations. C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal	10/03/2025		SmPC and PL	

	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 Change(s) in the Summary of Product 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 4.8 of the SmPC and section 4 of the Package Leaflet to change the frequency category of DILI (Drug-induced liver injury) from "not known" to "rare", following approval of the same changes in the reference product. C.I.2.a (IB) - To update sections 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 5.1, 5.2, and 5.3 of the SmPC, as well as sections 2 and 4 of the Package Leaflet, in order to align with the reference product by bringing the annexes in line with the QRD template and the SmPC guideline.				