Fingolimod 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 IB /	C.9 Introduction of, or change(s) to, the	02/03/2026			

[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/0000326132	obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted C.9.b - To update RMP for Fingolimod Accord 0.5 mg hard capsules in line with European Public Assessment Report of reference product (Gilenya) risk management plan (Version 21.1; dated 23-Jul-2025) published by EMA on 23-Sep-2025.				
Variation type IA / EMA/VR/0000320287	B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted	05/01/2026			
Variation type IA / EMA/VR/0000315998	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	16/12/2025			

	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				
Variation type IB / EMA/VR/0000267169	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 C.I.11.z - To update RMP in line with EPAR for RMP of reference product Gilenya published on 18 December 2024.	21/05/2025			
Variation type IB / EMA/VR/0000254070	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	14/03/2025	05/05/2025	SmPC, Annex II and PL	

	new additional data is required to be submitted by the MAH - Accepted C.I.2.a (IB) - To update section 4.3 of the SmPC in order to add suspected or confirmed progressive multifocal leukoencephalopathy (PML) as a new contraindication; update of section 4.4 of the SmPC to amend an existing warning on PML and to add a new warning on immune reconstitution inflammatory syndrome (IRIS) and update of section 4.8 of the SmPC in order to add IRIS as ADR with frequency not know. Furthermore, the educational materials are updated on information about IRIS and also updated to improve the general readability and better address key messages and recommendations for healthcare professionals and patients. The Package Leaflet and Annex II are updated accordingly. These updates follow the approval of the same changes in the reference product.				
Variation type IA / EMA/VR/0000226764	A. ADMINISTRATIVE CHANGES - A.6 Change in ATC Code / ATC Vet Code - Accepted	09/09/2024	04/04/2025	SmPC	
Article 61(3) / EMA/N/0000221326	- Notification acc. Article 61(3) - Accepted Update of the package leaflet to include the list of local representatives.	10/07/2024	04/04/2025	PL	