



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Fingolimod Accord

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
R/0011	Renewal of the marketing authorisation.	30/01/2025	04/04/2025	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Fingolimod Accord in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

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).



IA/0010/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	15/05/2024	04/04/2025	Annex II and PL	
IAIN/0009	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	06/05/2024	04/04/2025	SmPC and PL	
IA/0008	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	18/10/2023	n/a		
IB/0007	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	18/08/2023	10/05/2024	SmPC, Annex II and PL	
IAIN/0006/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release -	12/05/2023	10/05/2024	Annex II and PL	

	Not including batch control/testing B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
IAIN/0005	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	27/02/2023	n/a		
IB/0004/G	This was an application for a group of variations. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	08/02/2022	08/07/2022	SmPC	To update sections 4.4, 4.8, 5.1 and 5.2 due to the same changes being adopted for parent product Gilenya following assessment of the non-interventional final study report D2403 (long-term, prospective, multinational, parallel-cohort study monitoring safety in patients with multiple sclerosis newly started on fingolimod once daily or treated with another approved disease-modifying therapy). Consequently, the Annex IID is updated to remove the obligation to perform the PASS D2409. An updated RMP has been also provided.
PSUSA/1393/202102	Periodic Safety Update EU Single assessment - fingolimod	30/09/2021	n/a		PRAC Recommendation - maintenance
IB/0003	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by	26/07/2021	08/07/2022	SmPC and PL	To update subsections of Infections, Liver injury and Hepatobiliary disorders with a frequency not know (acute hepatic failure) following the safety assessment of the same change for the reference product.

	the MAH				
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