Apremilast 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 /	Outcome:	11/06/2026		SmPC	

[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/0000355526	Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted				
Variation type IB / EMA/VR/0000337482	Outcome: C.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.2.a) Implementation of change(s) for which no new additional data is required to be submitted by the holder - Accepted Type IB C.2.a - to update sections 4.4, 4.8 of the SmPC and section 4 of the leaflet in-line with the reference product information following assessment of same change in reference product Otezla (procedure EMA/PSUR/0000282235). Additionally, the MAH took the opportunity to update section 4.2 of the SmPC with the editorial changes in line with reference product information.	20/03/2026		SmPC and PL	
Variation type IB / EMA/VR/0000326527	Outcome: C. Safety, efficacy, pharmacovigilance changes - C.z Other variation - Accepted C.z (Type IB) – To update section 4.4 of the SmPC and section 2 of the PL to include the missing excipient warning for sodium, in line	19/02/2026		SmPC and PL	To update section 4.4 of the SmPC and section 2 of the PL to include the missing excipient warning for sodium, in-line with the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'. The MAH has also made several editorial updates in line with the QRD template. Section 9 of

	with the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'. The MAH has also made several editorial updates in line with the QRD template. Section 9 of the SmPC now includes the date of first authorisation, and section 10 has been updated with the correct EMA website address. In section 4.8, the wording on the "national reporting system listed in Appendix V" has been revised and grey shaded. In the PL, section 6 has been updated to add the relevant E numbers for excipients, in line with the SmPC.				the SmPC now includes the date of first authorisation, and section 10 has been updated with the correct EMA website address. In section 4.8, the wording on the "national reporting system listed in Appendix V" has been revised and grey shaded. In the PL, section 6 has been updated to add the relevant E numbers for excipients, in line with the SmPC.
Variation type IA / EMA/VR/0000321370	Outcome: B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a Up to 10-fold compared to the originally approved batch size - Accepted	19/01/2026			
Article 61(3) / EMA/N/0000317881	Outcome: - Notification acc. Article 61(3) - Accepted Update of the product information to introduce the following changes to the labelling: - to align the grey-shading of the pharmaceutical form in section '4. Pharmaceutical form and contents' of the 'Particulars to appear on the outer packaging' with all other presentations - to update 'For oral use' to 'Oral use' in section	07/01/2026		Labelling	

	'5. Method and route(s) of administration' of the 'Particulars to appear on the outer packaging' - to grey-shade all blister text of the 'Minimum particulars to appear on blisters or strips' for the wallet card initiation packs - to align the grey-shading of '2D barcode carrying the unique identifier included' in section '17. Unique identifier -2D barcode' of the 'Particulars to appear on the outer packaging' with all other presentations. - to harmonise the grey-shading of the marketing authorisation number in section '12. Marketing authorisation number(s)' of the 'Particulars to appear on the outer packaging' where applicable. Additionally, the MAH took the opportunity to introduce minor editorial amendments.				
Variation type IA / EMA/VR/0000280853	Outcome: This was an application for a group of variations. 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. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active	25/06/2025			

	substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted				