Remicade

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
Marketing Authorisation	- Transfer of a marketing authorisation -	26/09/2025	26/11/2025	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).

Transfer - H / EMA/T/0000294601	transfer of marketing authorisation from Janssen Biologics B.V. to Janssen Cilag International N.V.			Labelling and PL	
Variation type IB / EMA/VR/0000278107	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted	04/09/2025	N/A		
Variation type IB / EMA/VR/0000281967	This was an application for a group of variations. B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already	11/07/2025	N/A		

	approved manufacturer - Accepted 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.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.c Other changes to a test procedure (including replacement or addition) for a reagent, which does not have a significant effect on the overall quality of the active substance - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active 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				
Variation type II / EMA/VR/0000229576	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new	20/03/2025	26/11/2025	SmPC, Annex II, Labelling and PL	SmPC new text SmPC Section 4.4 Polysorbate 80 content Remicade contains 0.50 mg of polysorbate 80 (E433) in each dosage unit which is equivalent to 0.05 mg/ml. Polysorbates may cause allergic

	quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.4 and 6.1 of the SmPC and the respective sections of the PL to add information about polysorbates in line with revision 4 of the Annex to the EU Excipients Guideline. Additionally, minor editorial changes have been introduced throughout the PI. The MAH took also the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template. The initially proposed update to the SmPC section 4.8 to add the "paradoxical drug-induced immune disorders (e.g., new onset psoriasis)" with the frequency 'uncommon' has been refuted as it was considered that this issue is already adequately reflected in the current PI safety sections.				reactions. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000254551	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	14/03/2025	N/A N/A		
Variation type II / EMA/VR/0000224494	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or	30/01/2025		SmPC and PL	SmPC new text Section 4.4. A patient who requires surgery while on Remicade should be closely monitored for infectious and non-infectious complications, and appropriate actions should be taken (see section 4.8). Section 4.8 Injury,

	pharmacovigilance data - Accepted Update of sections 4.4 and 4.8 of the SmPC in order to add post-procedural complications (including infectious and non-infections complications) to the list of adverse drug reactions (ADRs) with frequency not known and update treatment recommendations for patients with a planned surgical procedure based on a cumulative review of literature, clinical trial and registry data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update details of local representatives of Germany and Slovenia.				poisoning, and procedural complications, Not known: Post-procedural complication (including infectious and non-infectious complications) For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000232112	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted	05/11/2024	N/A		
Article 61(3) / EMA/N/0000229075	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives.	01/10/2024	04/11/2024	PL	
Article 61(3) / EMA/N/0000225421	- Notification acc. Article 61(3) - Accepted	26/08/2024	04/11/2024	PL	

	Update of the package leaflet with revised contact details of local representatives				