Inflectra

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.I.11 Introduction of, or change(s) to, the	16/02/2026			

[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/0000323223	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 the RMP for Inflectra. The update ensures alignment with the latest RMP (version 18.0 dated 30 September 2025) submitted by Celltrion for Remsima, as part of the closing sequence for procedure EMEA/H/C/002576/X/0149.				
Variation type IB / EMA/VR/0000294606	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 (Type IB) – To update Sections 2, 4.4, and 6.1 of the SmPC and Sections 2 and 6 of the PL with information on the excipient polysorbate 80, in accordance with the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' and aligned with approved changes to the reference product Remicade.	10/09/2025		SmPC and PL	To update Sections 2, 4.4, and 6.1 of the SmPC and Sections 2 and 6 of the PL with information on the excipient polysorbate 80, in accordance with the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' and aligned with approved changes to the reference product Remicade.

Variation type IB / EMA/VR/0000269305	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 - To update 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. The change follows assessment of the same change for the reference product, Remicade. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI in line with the QRD template, updated the details of the local representative for IE and removed the local representative for UK (Northern Ireland).	27/05/2025		SmPC and PL	To update 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. The change follows assessment of the same change for the reference product, Remicade.