Otulfi

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 /		27/05/2026		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/0000343407	Outcome: 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 II / EMA/VR/0000296289	Outcome: This was an application for a group of variations. 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.c The product is a biological/immunological medicinal product and the change requires an assessment of comparability - 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.z Other changes - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted	12/02/2026		SmPC, Labelling and PL	

	B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.IV.1 Change of a measuring or administration device - B.IV.1.c Addition or replacement of a device which is an integrated part of the primary packaging - Accepted				
Variation type IA / EMA/VR/0000309715	Outcome: 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	04/11/2025			
Variation type IB / EMA/VR/0000285631		11/08/2025	09/09/2025	SmPC and PL	

	Outcome: This was an application for a group of variations. 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 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 HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.2.a (Type IB) – To update Sections 4.5 and 5.2 of the SmPC in order to add drug-drug interaction information, and to update Sections 4.8 and 5.1 of the SmPC with patient exposure numbers based on results from study CNTO1275CRD1003. The changes follow assessment of the same changes for the reference product, Stelara (II/0107). In addition, the MAH took the				

	opportunity to implement editorial changes to align the PI with the QRD template. C.I.2.a (Type IB) – To extend the indication to include the treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy. The PI is updated accordingly. The changes follow assessment of the same changes for the reference product, Stelara (II/0108). C.I.z (Type IB) – To include the needle gauge size in Section 6 of the SmPC for the 45 mg and 90 mg Otulfi solution for injection in a pre-filled syringe presentations (EU/1/24/1863/001, 002). In addition, the MAH took the opportunity to update the PI with information on the polysorbate excipient, based on the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'.				
Variation type IA / EMA/VR/0000280806	Outcome: 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.a Minor changes to an	23/06/2025			

	approved test procedure - Accepted				