



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Talmanco

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, please 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.2 Change(s) in the Summary of Product	02/09/2024	26/09/2024	SmPC and PL	To Extend the Indication to include paediatric use

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/0000177149	<p>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</p> <p>To Extend the Indication to include paediatric use (from 2 years to 17 years) based on study 4 (H6D-MC-LVHV [LVHV]) - A 24-week placebo-controlled efficacy and safety study with an open-label long-term extension phase. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated accordingly. Furthermore, the PI is aligned with the QRD template and additional editorial changes have been implemented in line with the reference product. Furthermore the MAH has taken this opportunity to update the local representatives in AT, CY, ET, ES, IE, LT, LV, PL and PT.</p>				<p>(from 2 years to 17 years) based on study 4 (H6D-MC-LVHV [LVHV]) - A 24-week placebo-controlled efficacy and safety study with an open-label long-term extension phase. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and Labelling are updated accordingly. Furthermore, the PI is aligned with the QRD template and additional editorial changes have been implemented in line with the reference product. Furthermore the MAH has taken this opportunity to update the local representatives in AT, CY, ET, ES, IE, LT, LV, PL and PT.</p>
Variation type IA / EMA/VR/0000169854	<p>B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted</p>	07/03/2024	N/A		