Segluromet

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
Article 61(3) /	- Notification acc. Article 61(3) - Accepted	21/11/2025		PL	

[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/N/0000312917	Update of the package leaflet with revised contact details of local representatives.				
Variation type IA / EMA/VR/0000289536	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	20/08/2025	N/A		
Variation type IB / EMA/VR/0000262413	C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Implementation of wording agreed by the competent authority + QRD update - Accepted To update section 4.4 of the SmPC to introduce a warning on aggravation of MELAS (Mitochondrial Encephalopathy with Lactic Acidosis, and Stroke-like episodes) syndrome and MIDD (Maternal inherited diabetes and deafness) in patients taking metformin with known mitochondrial diseases following the outcome of PSUSA/00002001/202404. The Package Leaflet is updated accordingly. In addition	02/05/2025		SmPC and PL	

	the MAH has updated the details of the Local Representatives for Lithuania/Denmark/Germany/Estonia/Norway/Spain/Iceland/Sweden/Latvia and updated to the latest QRD template.				