



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ovaleap

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	13/03/2025	16/04/2025	SmPC and PL	To update sections 4.2 and 4.4 of the SmPC and

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/0000248727	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. C.I.2.a (IB) - To update sections 4.2 and 4.4 of the SmPC and section 3 of the Package Leaflet in order to align the wording with current clinical practice and to remove Estradiol and follicle number thresholds associated with signs of Ovarian Hyperstimulation Syndrome (OHSS).				section 3 of the Package Leaflet in order to align the wording with current clinical practice and to remove Estradiol and follicle number thresholds associated with signs of Ovarian Hyperstimulation Syndrome (OHSS).
Variation type IA_IN / EMA/VR/0000247845	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	05/02/2025	N/A		