Emadine

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 II / EMA/VR/0000222987	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission	20/02/2025		SmPC, Labelling and	The SmPC section 6.5 has been updated to reflect the new container closure: "5 ml solution in a bottle (LDPE) with a dispensing plug (LDPE) and a tamper

[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).

	Regulation (EC) No 1234/2008. B.II.e.1.a Qualitative and quantitative composition - B.II.e.1.a.3 Sterile medicinal products and biological/ immunological medicinal products - Accepted B.II.e.4 Change in shape or dimensions of the container or closure (immediate packaging) - B.II.e.4.c Sterile medicinal products - Accepted			PL	evident closure screw cap (PE)" (EU/1/98/095/001) and to reflect the deletion in section 8 of the EU number for the removed 10 mL presentation (EU/1/98/095/002). The Labelling and the Package Leaflet have been updated accordingly to update the container closure system and the removal of the 10 mL presentation.