ECALTA

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 /	This was an application for a group of	09/09/2025		SmPC and 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/VR/0000282338	variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority. - Accepted C.I.z (Type IB) – To update Sections 2 and 4.4 of the SmPC and Sections 2 and 6 of the PL with information on the excipient polysorbate 80, based on the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'. Additionally, the MAH implemented editorial				

	changes by introducing the full term "invasive candidiasis including candidaemia" before the abbreviation "ICC" in Section 4.8 of the SmPC, retaining only the abbreviation in Section 5.1, updating the local representative information for IE in the PL, and removing the representative for the United Kingdom (Northern Ireland) in line with the QRD template. C.I.z (Type IA) – To update Section 5.1 of the EU SmPC to include a weblink to the European Medicines Agency (EMA) referencing susceptibility testing breakpoints established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for anidulafungin.				