Ifirmasta

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 /	This was an application for a variation	08/05/2025		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/0000258251	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z - To update sections 4.4 and 4.8 of the SmPC with new safety information regarding intestinal angioedema following PRAC recommendations on signals adopted on 31 October 2024. Sections 2 and 4 of the Package Leaflet were updated accordingly. In addition, the MAH took the opportunity to include minor editorial corrections in the following languages: EN, CS, DA, EL, FR, HU, IT, IS, LV, PL, RO SV and SL. Finally, for Ifirmasta only, the information related to the local representatives for Hungary was updated and (UK) Northern Ireland local representative was deleted in section 6 of the Package Leaflet according to the latest QRD template update 10.4.				