Galafold

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 /	C.I HUMAN AND VETERINARY MEDICINAL	22/08/2025		SmPC,	To add an amenable mutation to section 5.1 of the

[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/0000285583	PRODUCTS - C.I.z Other variation - Accepted To add an amenable mutation to section 5.1 of the SmPC. In addition the MAH took the opportunity to update the contact details of the local representatives in HR and RO and to update the outer packaging to better describe and ensure correct dosing.			Labelling and PL	SmPC. In addition, the MAH took the opportunity to update the contact details of the local representatives in HR and RO and to update the outer packaging to better describe and ensure correct dosing.