



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Carbaglu

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	25/11/2025		SmPC, Annex	

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/0000291322	PRODUCTS - C.I.z Other variation - Accepted To correct an error regarding the rate of decrease in renal clearance in patients with mild, moderate and severe renal impairment in section 5.2. Also the MAH has taken the opportunity to remove "F-" from the various addresses in France.			II, Labelling and PL	
Variation type IB / EMA/VR/0000281024	B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted	07/08/2025	N/A		
PSUR / EMA/PSUR/0000274412	- -				Maintenance