Cerdelga

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
Article 61(3) /	- Notification acc. Article 61(3) -	16/05/2025		Labelling and	

[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/N/0000257011	Update of the labelling for Cerdelga 21 and 84 mg hard capsules (EU/1/14/974/001-004) to introduce a QR code and URL under section '5. Method and route of administration' of the outer packaging. The QR code and URL provide access to a website containing the package leaflet in the selected language, contact information for further information about the product and information for reporting side effects. Additionally, the package leaflet was updated with revised contact details of a local representative.			PL	
Variation type II / EMA/VR/0000245058	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted - - Accepted Submission of the final report from study ELIGLC06913 listed as a category 3 PASS in the RMP. This is a drug utilisation study of eliglustat for the treatment of Gaucher Disease Type 1 in Europe using electronic healthcare records.	10/04/2025			