



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Competact

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 <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
Variation type IB /	C.I.3 Change(s) in the Summary of Product	08/04/2025		SmPC and PL	

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



EMA/VR/0000262689	<p>Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR: implementation of wording agreed by the competent authority - Accepted</p> <p>C.I.3.z (Type IB) - To update section 4.4 (Special warnings and precautions for use) of the SmPC and section 2 (Warnings and precautions) of the Package Leaflet with MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD) following PRAC recommendation regarding signal assessment of MELAS Syndrome/MIDD.</p>				
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