Cinacalcet Viatris

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	07/10/2025		SmPC,	To update Section 3 of the SmPC and Section 6 of

[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/0000302017	PRODUCTS - C.I.z Other variation - Accepted C.I.z (Type IB) – To update Section 3 of the SmPC and Section 6 of the PL by adding the short term '(tablet)', and Section 1 of the blister labelling texts by adding gray shading to the text 'film-coated'. In addition, the MAH took the opportunity to implement editorial changes, by correcting typographical errors, updating the contact information of the local representative for CZ in the PL, removing the local representative for UK(NI) in line with the QRD template, and implemented minor editorial changes in the DE, SE and SK PI to correct typographical errors and to delete the MAH address from the blister in line with the EN PI.			Labelling and PL	the PL by adding the short term '(tablet)', and Section 1 of the blister labelling texts by adding gray shading to the text 'film-coated'.
Variation type IB / EMA/VR/0000268655	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e) Container closure system - B.II.e.z Other variation - Accepted	10/07/2025	N/A		