Clopidogrel Zentiva

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 /	Outcome:	27/07/2026		SmPC,	

[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/0000360514	C.7 Deletion of: - C.7.b) a strength - Accepted To delete the 300 mg strength from the Clopidogrel Zentiva marketing authorisation (EU/1/08/465/015, /016. /017, and /020}. Furthermore the applicant has taken the opportunity to update the local representative in ET and provide minor editorial corrections in all annexes. Minor editorial changes beyond those presented in the EN annexes, have been propose in the ES and SK Annexes. In addition the quality chapter connected solely to Clopidogrel Zentiva 300 mg, film-coated tablets have been removed from the dossier including manufacturing sites.			Labelling and PL	
Variation type IA / EMA/VR/0000321353	Outcome: This was an application for a group of variations. B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted	16/01/2026			

Variation type IA_IN / EMA/VR/0000248524	Outcome: B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.3 New certificate from a new manufacturer (replacement or addition) - Accepted	27/02/2025			
PSUR / EMA/PSUR/0000336095	EURD: PSUSA/00000820/202511 Active substance: acetylsalicylic acid / clopidogrel, clopidogrel Outcome: Maintenance	09/07/2026			