



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clopidogrel/Acetylsalicylic acid 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, 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
Variation type IA /	This was an application for a group of	02/05/2025		Annex II 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/VR/0000268788	<p>variations.</p> <p>A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted</p> <p>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</p> <p>A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted</p>			PL	
Variation type IB / EMA/VR/0000246078	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc.	27/02/2025		SmPC and PL	

	<p>Implementation of wording agreed by the competent authority. - Accepted</p> <p>C.I.z (IB) - To update sections 4.3 and 4.6 of the SmPC and section 2 of the Package Leaflet to introduce information on "NSAID-containing medicinal products (for systemic use) and use during pregnancy", following the CMDh recommendation (EMA/CMDh/492082/2024). Furthermore, the Marketing Authorisation Holder has taken the opportunity to implement updates in the list of local representatives.</p>				
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