EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Amlodipine-Valsartan Mylan

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 IA /	This was an application for a group of	23/07/2025		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/0000287321	variations. 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 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			PL	
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		
Variation type IA / EMA/VR/0000281161	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	26/06/2025	N/A		

Article 61(3) / EMA/N/0000278337	- Notification acc. Article 61(3) - Update of sections '1. Name of the medicinal product' of the Minimum particulars to appear on blisters or strips in the labelling for all presentations to introduce grey shading of the INN 'amlodipine/valsartan'.	19/06/2025		Labelling	
Variation type IB / EMA/VR/0000246731	This was an application for a group of variations. C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted 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. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon. - Accepted	12/05/2025		SmPC and PL	To update sections 4.5 and 4.8 of the SmPC to add interaction with tacrolimus and to remove Anorexia, Hypercalcaemia, Hyperlipidaemia, Hyperuricaemia and Hypokalaemia from the list of adverse reaction, respectively, following assessment of the same changes in the reference product. The Package Leaflet has been updated accordingly. To update section 4.4 of the SmPC and sections 2 and 4 of the Package Leaflet to implement the signal recommendations on "Angiotensin II receptor blockers (ARBs): azilsartan; candesartan; eprosartan; irbesartan; losartan; olmesartan; telmisartan; valsartan (single ingredient and fixed dose combinations) – Intestinal angioedema" (EPITT no 20104)' adopted at the 31 October 2024 PRAC meeting.

	C.I.2.a (IB) - To update sections 4.5 and 4.8 of the SmPC to add interaction with tacrolimus and to remove Anorexia, Hypercalcaemia, Hyperlipidaemia, Hyperuricaemia and Hypokalaemia from the list of adverse reaction, respectively, following assessment of the same changes in the reference product. The Package Leaflet has been updated accordingly. C.I.z (IA) - To update section 4.4 of the SmPC and sections 2 and 4 of the Package Leaflet to implement the signal recommendations on "Angiotensin II receptor blockers (ARBs): azilsartan; candesartan; eprosartan; irbesartan; losartan; olmesartan; telmisartan; valsartan (single ingredient and fixed dose combinations) – Intestinal angioedema" (EPITT no 20104)' adopted at the 31 October 2024 PRAC meeting. Furthermore, the Marketing Authorisation Holder has taken the opportunity to implement editorial changes in line with the reference product and to remove the United Kingdom (Northern Ireland) from the list of local representatives in the Package Leaflet. In addition, the MAH has taken the opportunity to add the abbreviated term for the pharmaceutical form in Section 3 of the SmPC, Section 1 of Labelling and Section 6 of the PL to match the use of the shortened form in the packaging materials.				