Micardis

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 /	B.II.b.3 Change in the manufacturing	10/09/2025			

[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/0000294339	process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Deletion of one manufacturing process of the drug product manufacturing processes - Accepted				
Variation type IB / EMA/VR/0000242970	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted To change the description "angiotensin II receptor antagonists" to "angiotensin II receptor blockers" throughout the annexes. In addition the MAH has corrected the Sorbitol quantity in the 80 mg tablets and brought the annexes in line with the current QRD version and updated the local representative in Norway.	03/04/2025		SmPC, Annex II and PL	To change the description "angiotensin II receptor antagonists" to "angiotensin II receptor blockers" throughout the annexes. In addition the MAH has corrected the Sorbitol quantity in the 80 mg tablets and brought the annexes in line with the current QRD version and updated the local representative in Norway.
Variation type IA / EMA/VR/0000244321	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 A. ADMINISTRATIVE CHANGES - A.7	24/02/2025		Annex II and PL	

	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				