Tolura

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.2 Change(s) in the Summary of Product	17/07/2025		SmPC and PL	To change the description "angiotensin II receptor

[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/0000279934	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.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.2.a (Type IB) – To change the description "angiotensin II receptor antagonists" to "angiotensin II receptor blockers" throughout the annexes. The change follows assessment of the same change to the reference product, Micardis (EMA/VR/0000242970). C.I.2.a (Type IB) – To update the SmPC and PL following assessment of the same change to the reference product, Micardis (WS/2489), including: - An update of Sections 4.2, 4.4 and 4.9 of the SmPC with information related to the removal of telmisartan by haemodialysis. - An update of Section 4.7 of the SmPC, replacing the terms “dizziness”				antagonists" to "angiotensin II receptor blockers" throughout the annexes. The change follows assessment of the same change to the reference product, Micardis (EMA/VR/0000242970). To update the SmPC and PL following assessment of the same change to the reference product, Micardis (WS/2489), including: - An update of Sections 4.2, 4.4 and 4.9 of the SmPC with information related to the removal of telmisartan by haemodialisis. - An update of Section 4.7 of the SmPC, replacing the terms “dizziness” and “drowsiness” by “syncope” and “vertigo” to align with ADR table in section 4.8 of the SmPC. - An update of Section 4.8 of the SmPC in order to include “hyponatremia” to the list of adverse drug reactions (ADRs) with frequency “rare”, based on post marketing data and literature - An update of Section 5.3 of the SmPC regarding the effect of telmisartan on male and female fertility

	and “drowsiness” by “syncope” and “vertigo” to align with ADR table in section 4.8 of the SmPC. - An update of Section 4.8 of the SmPC in order to include “hyponatremia” to the list of adverse drug reactions (ADRs) with frequency “rare”, based on post marketing data and literature - An update of Section 5.3 of the SmPC regarding the effect of telmisartan on male and female fertility Additionally, the MAH took the opportunity to implement editorial changes to align with the PI of the reference product, to combine the SmPC for all strengths, to align with the QRD template, and to add information regarding the excipient sodium throughout the PI based on the Annex to the European Commission guideline on ‘Excipients in the labelling and package leaflet of medicinal products for human use’.				
Variation type IA / EMA/VR/0000268268	This was an application for a group of variations. B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the	30/04/2025	N/A		

	finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted				
Variation type IB / EMA/VR/0000247066	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH - Accepted To updated sections 4.4 and 4.8 of the SmPC to add new safety information regarding intestinal angioedema following PRAC recommendation EMA/PRAC/499603/2024; EPITT 20104. The package leaflet is updated accordingly. In addition the MAH has taken the opportunity to make minor editorial corrections in several translations.	18/03/2025		SmPC and PL	To updated sections 4.4 and 4.8 of the SmPC to add new safety information regarding intestinal angioedema following PRAC recommendation EMA/PRAC/499603/2024; EPITT 20104. The package leaflet is updated accordingly. In addition the MAH has taken the opportunity to make minor editorial corrections in several translations.