



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Yuvanci

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.III.1.a European Pharmacopoeial	16/09/2025	N/A		

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/0000295502	Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted				
Variation type II / EMA/VR/0000280219	<p>C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted</p> <p>Update of section 4.8 of the SmPC in order to update safety information based on final results from Phase 3 study AC-077A301 A DUE (Open Label); this is a multi-center, double-blind, randomized, active-controlled, triple-dummy, parallel-group, group-sequential, adaptive study conducted to evaluate the efficacy and safety of Macitentan/Tadalafil Fixed Dose Combination, versus macitentan or tadalafil monotherapy in participants with PAH. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to update the active metabolite to its INN name throughout the PI.</p>	04/09/2025		SmPC and PL	
Variation type IB / EMA/VR/0000263183	This was an application for a group of variations.	29/04/2025	N/A		

B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) - Accepted

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

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