Voriconazole Accord

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	06/10/2025	17/10/2025	SmPC and PL	To update Sections 4.3 and 4.5 of the SmPC to add

[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/0000296347	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 update Sections 4.3 and 4.5 of the SmPC to add a contraindication for concomitant use with finerenone based on post-marketing data and review of the literature. Section 2 of the PL was updated accordingly. In addition, changes were performed to section 4.5 of the SmPC. The drug-drug interaction table is now ordered on therapeutic class and interactions affecting voriconazole are given first, followed by those interactions resulting in clinically relevant changes. Furthermore, Section 4.2 of the SmPC is updated in-line with reference product to update the available alternate formulation details. The changes follow assessment and approval of the same changes for the reference product, VFEND.				a contraindication for concomitant use with finerenone based on post-marketing data and review of the literature. Section 2 of the PL was updated accordingly. In addition, changes were performed to section 4.5 of the SmPC. The drug-drug interaction table is now ordered on therapeutic class and interactions affecting voriconazole are given first, followed by those interactions resulting in clinically relevant changes. Furthermore, Section 4.2 of the SmPC is updated in-line with reference product to update the available alternate formulation details. The changes follow assessment and approval of the same changes for the reference product, VFEND.
Variation type IB / EMA/VR/0000286652	B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test	08/08/2025	N/A		

	procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted				
Variation type IA_IN / EMA/VR/0000287885	B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted	25/07/2025	17/10/2025	Annex II and PL	
Article 61(3) / EMA/N/0000269325	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with the addition of contact details of local representatives	07/05/2025		PL	
Variation type IA_IN / EMA/VR/0000255783	B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	17/03/2025	N/A		