Voriconazole Hikma

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	09/12/2025	19/12/2025	SmPC and PL	To update Sections 4.3 and 4.5 of the SmPC in

[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/0000310244	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 in order to add a contraindication for concomitant use with finerenone based on post-marketing data and review of the literature. The Package Leaflet was updated accordingly. In addition, changes were made 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. The changes follow approved changes for the reference product Vfend.				order to add a contraindication for concomitant use with finerenone based on post-marketing data and review of the literature. The Package Leaflet was updated accordingly. In addition, changes were made 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. The changes follow approved changes for the reference product Vfend.